Ninety-Eighth meeting of the Human Tissue Authority Board

Date: 4 November 2021

Time: 10.00 -12.00 (Main meeting)

12.00 - 12.20 (Private session - Board and incoming CEO)

Venue: Zoom

Protective Marking: OFFICIAL

Agenda

1. Welcome and apologies (LB) (10.00-10.15)
2. Declarations of interest * (LB)
3. Minutes of 15 July 2021 meeting cover paper (HTA 19/21) * (LB)
   Annex A – Minutes from the 15 July Board meeting (HTA 19a/21) * (LB)
4. Matters arising from 15 July 2021 meeting (HTA 20/21) * (LB)

Regular reporting

5. Chair's Report (Oral) (LB) (10.15-10.35)
6. Chief Executive's Report (HTA 21/21) * (LD) (10.35-10.55)

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

Committee and Working Groups

7. Audit and Risk Assurance Committee Update (HTA 22/21) * (GC) (10.55-11.05)

Development Programme

8. Development Programme Update (HTA 23/21) * (LD) (11.05-11.10)

Policy

9. HTA Fees – proposals for 2022/23 (HTA 24/21) (RS) (11.10-11.25)

10. Living Donation – 12-month review of panel process (HTA 25/21) (ANH) (11.25-11.40)

11. Police Referral Policy (HTA 26/21) (ANH) (11.40-11.50)
    Annex A Police Referral Policy Document (HTA 26a/21)

Any Other Business

12. Any Other Business (Oral) (LB) (11.50-12.00)

Meeting Close 12.00

* Indicates agenda items which are for information only

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 19/21

Agenda item: 03

Author: Alison Margrave

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Minutes of the HTA Board Meeting held 15 July 2021

Purpose of paper

1. To seek approval that the minutes of the HTA Board Meeting held 15 July 2021 are a true record of the meeting.

Decision making to date

2. The minutes were approved by the Chief Executive and Chair before being distributed to the Board.

Action required

3. To approve the minutes of the HTA Board Meeting held 15 July 2021 as a true record of the meeting.

Background

4. The draft minutes from the HTA Board meeting held 15 July 2021 were issued to Board members via email on 10 August 2021. Board members were asked to provide any feedback, comments, or corrections to these minutes no later than 25 August 2021. By this deadline the HTA Office had only received positive confirmation that the minutes were accurate, and no amendments were received.

Minutes of the ninety-seventh meeting of the Human Tissue Authority Board

Date: 15 July 2021

Time: 10.00-12.00 (Meeting held in Public)

Venue: Zoom

Protective Marking: OFFICIAL

Attendees:

Board Members

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

Observers

Amy Parsons, Policy Manager, DHSC

Apologies

Nicolette Harrison, Director of Regulation, HTA
Marina Pappa, Deputy Director Health Ethics, DHSC
Dylan Parrin, Senior Policy Manager, DHSC

HTA attendees

Allan Marriott-Smith, CEO
Louise Dineley, Director of Data, Technology and Development
Richard Sydee, Director of Resources
Christopher Birkett, Head of Regulation
Dr Robert Watson, Head of Regulation
Nima Sharma, Board Secretary (minutes)

Item 1 – Welcome and apologies

1. The HTA Chair welcomed Board Members, the Executive, observers from the Department of Health and Social Care and members of the public to the ninety seventh meeting of the HTA's Board.

2. The Chair provided an introduction on the role of the HTA and informed all of those in attendance that the meeting would be recorded and made available on the HTA's YouTube channel.

Item 2 – Declarations of interest

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

Item 3 – Minutes of 6 May 2021 meeting [HTA 12/21]

4. The Chair asked for any comments on the factual accuracy of the minutes from the last meeting. There were no further comments.

Item 4 – Matters Arising from the 6 May 2021 meeting [HTA 13/21]

5. The Chair asked if there were any comments on the matters arising note from the last meeting. There were no further comments.

Item 5 – Chair's Report [Oral]

6. The Chair provided an update to the Board on several items set out below:

<u>Changes to sponsor team at Department of Health and Social Care (DHSC)</u>

- There would be several changes to the HTA's sponsor team, with Mark Davies retiring at the end of July and Marina Pappa moving into another role

within the Department. The Chair thanked Mark and Marina for their contributions and wished them well for the future.

- The Chair informed the Board that she had attended a number of meetings with DHSC and attended a meeting with Chairs and Ministers regarding the Health and Care Bill.

Objective setting meetings

- The objective setting meetings for Board Members had taken place and the objectives for 2021/2 have been agreed.

Staff changes

- Members were informed that Nima Sharma, Board Secretary would be returning to her previous role as a Regulation Manager and thanked her for her support to the Board. The Board was informed that an interim appointment had been made to provide Board support until the position is filled substantively

- Members were also informed that Allan Marriott-Smith would be leaving the HTA in the autumn and that this meeting would likely be his last. Allan was thanked for the extraordinary contribution he had made in the last six years as CEO.

Item 6 – Chief Executive's Report [HTA 14/21]

7. Allan Marriot-Smith presented this paper to the Board.

8. He asked the Board to note the revised presentation of the risk register which was trialled at the May Board meeting and approved by the Audit and Risk Assurance Committee (ARAC) in June. The new presentation has a particular focus on the Executive's assessment of the dynamics of each risk over time.

9. An update was provided on Virtual Regulatory Assessment (VRAs) and background was provided as to why this model had been implemented. It

was highlighted that a test and learn approach had been implemented initially in the Human Application (HA) sector and had been recently rolled out in the other sectors the HTA regulates under the Human Tissue Act.

10. The Board was informed that the HTA is hoping to resume HA sector inspections in the autumn after appropriate risk assessments and with personal protective equipment available to all Regulation Managers.

11. An update was provided on the HTA's current vacant roles. Since the organisational restructure was agreed in May, seven and a half (out of ten and a half) vacancies had been filled. In addition, the Head of Communications role which became vacant subsequently has also been filled. Regarding the current assessment of strategic risk four, the Board was informed that the risk would be within tolerance once all the posts are filled, and new staff inducted into the organisation.

12. It was confirmed that the HTA's website redevelopment project was nearing completion having entered the public beta phase following a positive assessment from NHS X.

13. Thanks were extended to all those who had been involved in the amendments to Code D, which was in the process of going through Parliamentary approval.

14. Richard Sydee provided an update on the HTA's financial position at the end of quarter one.

15. The Board was referred to page 14 which provided details of the current financial position. The Board was informed that the HTA had a surplus income due to increased license fee income in quarter one and lower staff salary as a result of vacant posts. There was increased income in quarter one as a result of new licence applications.

16. The Board was provided with details on the HTA's debt position resulting from unpaid licence fees. The Board was given assurance that this debt is small as a proportion of total fees and does not affect the HTA operationally.

17. The Board requested that future CEO reports contain better visibility of equality and diversity data across the HTA. The Executive agreed that this would be provided in the next iteration of the CEO report.

18. Board Members were also keen for further information on staff wellbeing to be presented to the Board, particularly in light of the continued pressures on staff due to home working.

Action 1: The CEO report presented at the November Board meeting will include data on equality and diversity across the HTA and an update on staff wellbeing.

Item 7 Incident Analysis and Surveillance Presentation (HTA 15/21)

19. Chris Birkett and Dr Robert Watson presented this item.

20. The presentation provided an outline for the statutory requirement for reporting incidents within the Organ Donation and Transplantation and Human Application sectors and the HTA's own requirement for the reporting of incidents in the Post-Mortem sector. Information on trends within each sector was provided during the meeting.

21. It was highlighted that the Post-Mortem team had seen a decrease in reported 'serious security breaches' and in the 'any other incidents' categories. Similarly, there had been a reduction in reported incidents within the ODT (Organ Donation and Transplantation) (Organ Donation and Transplantation) sector, although the most reported incidents remain 'damage to organ upon retrieval.'

22. The Board noted that release of the wrong body and loss of an organ, are the categories most frequently reported, often indicating traceability issues. As a result, the HTA has developed guidance on how these risks can be mitigated.

23. For the HA sector, the Board noted that the majority of incidents were linked to procurement activities and that reported incidents within the sector had remained relatively stable over the period reported.

24. The Board was also asked to note that there is work being carried out with NHS Blood and Transplant to decide whether HHV8 (Human Herpesvirus 8) should be included as a mandatory test for deceased organ donation.

25. The Board was keen for the Executive consider the way in which incidents could be further reduced by sharing learning across the sectors, for example, through the use of webinars.

26. The Board noted the content of this presentation.

Item 8 Membership to Committees and Working Groups (Oral)

27. Allan Marriott-Smith provided an update on this item.

28. The membership of the Remuneration Committee has been reviewed and Glenn Houston will step down as he focuses on other responsibilities, he will be replaced by Ellen Donovan.

29. It was also noted that the Terms of Reference for the Remuneration Committee would need to be amended to be in line with current best practice in governance. The changes would reflect the expectation that the Chair of the Board should not chair the Remuneration Committee. A proposal to this effect would come to Board Members outside this meeting and, if the changes were ratified, Ellen Donovan would be appointed Chair of the Remuneration Committee instead of Lynne Berry.

30. For the other working groups, revised proposals would be developed under the Communication and Stakeholder Engagement Strategy which will be produced by the end of the year.

31. An update was provided on ongoing pieces of work with partner bodies, including the use of tissue blocks and slides from coronial Post-Mortems for a scheduled purpose (in partnership with the Royal College of Pathologists and the British Medical Association).

32. The Board noted the content of this update.

Item 9 Audit and Risk Assurance Committee (ARAC) Update (Oral)

33. Richard Sydee provided an oral update to the Board.

34. He informed the Board that ARAC had signed off the internal audit plan and received an update on cyber security (a standing agenda item) at the last meeting.

35. The Annual accounts were signed off and were being laid in parliament today (15 July 2021).

36. The Board was asked to note that ARAC had reviewed the current risk tolerances for each of the risks and had noted where these were above tolerance and the plans to bring them within the agreed level. ARAC would monitor the risks on behalf of the Board.

37. The content of this update was noted.

Item 10 Development Programme (HTA 17/21)

38. Louise Dineley presented this report and provided a progress update for Quarter one and the proposed deliverables in Quarter two. A more detailed report had been provided to ARAC.

39. The Board requested that more detail be provided about the Data Alliance Partnership at the November meeting.

40. The Board was keen to understand how well the proposed operating model has been understood by staff. They were informed that there is work being done across the organisation to ensure a collaborative approach is taken to the changes and with Regulation Managers actively involved in taking some of this work forward.

41. The Board was also informed of the plan to bring a change specialist into the HTA to assist with embedding change within the organisation.
The Board acknowledged this and welcomed the next update which should include assurance on the governance and leadership of the Programme.

42. The Board noted the content of the report.

Action 2: The Development Programme Update presented to the November Board meeting should have a greater emphasis on governance and leadership of the Programme.

Item 11 The HTA Beyond COVID-19 Restrictions

43. Richard Sydee presented this item.

44. The presentation provided information on the plans for staff to commence office working as well as recommence site visit inspections. The Senior Management Team is mindful of the impact on staff of a return to using public transport, which is known to be a concern for some.

45. The update included a particular focus on improving internal processes and better targeting of regulatory interventions such as virtual regulatory assessments, and tools to help better assess regulatory risk including through improved data sharing. It also touched on the opportunities presented from co-location with other regulators.

46. The Board noted the content of this update.

Item 12 Questions from Observers

47. There were no specific pre-submitted questions from observers for this item. The CEO provided some observations about the HTA's future strategy and the current landscape including the introduction of deemed consent for deceased organ donation.

Item 13 Any Other Business

48. There was no other business raised.

49. The Chair concluded the meeting by thanking everyone present and, those who had observed the meeting.

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 20/21

Agenda item: 04

Author: Alison Margrave

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Matters Arising from HTA Board meeting 15 July 2021

Action 1: The CEO report presented at the November Board meeting will include data on equality and diversity across the HTA and an update on staff wellbeing.

Executive response: The CEO report includes further detail on equality, diversity and inclusion as requested, see agenda item 6.

Action 2: The Development Programme update presented to the November Board meeting should have a greater emphasis on governance and leadership of the Programme.

Executive response: Report now includes a recap on governance and leadership of the Programme, see agenda item 8.

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 21/21

Agenda item: 06

Author: Louise Dineley,
Director of Data, Technology and Development

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Chief Executive's Report

Purpose of paper

1. This paper gives an overview of the HTA's performance during the period July to September 2021 (Quarter 2).

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

Decision making to date

3. The SMT (Senior Management Team) approved this paper for presentation to the Board on 21 October 2021.

Action required

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

Strategic risk

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

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

   Regarding risk one, routine site visit inspections have now re-started alongside Virtual Regulatory Assessments (VRAs). A full inspection schedule, comprising a mixture of VRAs and site visits at broadly similar levels to pre-pandemic, have been scheduled for the remainder of the business year.

Regulatory overview

7. Annex C to this paper contains a summary of regulatory activity during quarter two.

8. VRAs are continuing to be embedded into our regulatory toolkit, having been expanded into all sectors during quarter two, alongside a return to site visit inspections, such as through hybrid inspections.

9. One licence revocation took place in quarter two in the Research sector. There were 14 new licence applications. These included eight in the HA sector, four in the Research sector, one in the PM sector and one in the Anatomy sector.

10. Follow-up work continued during quarter two to support licensing changes after the end of the six-month period for issuing new import and export licences following the end of the UK Transition Period, with licences for movement of tissue between GB and EEA being needed from the date of first import or export after 30 June 2021. Of the eight HA applications mentioned, five of them were associated with transition.

11. The HTA's activity to implement the regulatory changes arising from the end of the Transition Period was completed at the end of quarter two. Further activity will be considered if there are changes to the Northern Ireland Protocol, that impact on human tissue.

12. Three Regulatory Decision Meetings (RDMs) were held in quarter two, two in the Human Application (HA) sector and one in the Organ Donation and Transplantation (ODT) sector. This resulted in a police referral consideration by SMT.

13. Living donation case numbers have started to recover but have not returned to pre-pandemic levels of activity. The Head of Regulation for this sector continues to meet monthly with the Lead Nurse for living donation at NHS Blood and Transplant.

14. Work has also continued to support a police investigation of a case referred by the HTA in quarter one of the 2020/21 business year and on several incidents and regulatory matters reported to us during quarters one and two, covering a range of sectors.

Development

Stakeholder Engagement

15. The HTA facilitated two regulatory round table discussions with sector representatives, exploring innovation in the Human Application sector and retention and access to blocks and slides produced at post-mortem examination for research. The round-table model is an approach the HTA is keen to develop to explore opportunities for development, innovation or problem solving with stakeholders.

Communications & Engagement

17. In the last quarter a revised working strategy to HTA Communications & Engagement has been developed. This working strategy has included a re-framing of previous communications and engagement methods to support the HTA's strategic priorities. Changes include a focus on social media, the testing of

alternative approaches to engagement and the continued development of accessible content.

Development Programme

18. Progress continues to be made on the projects within the Development Programme. More detail on the Programme is provided in paper (HTA 23/21, agenda item 8).

HTA Website Redevelopment Project

19. The HTA launched its new website at the end of quarter one. Over the last six weeks work has continued to further develop and enhance user experience of the HTA website. We will be monitoring the website activity to assess user experience and to identify any further development that may be required in advance of a “go live” assessment with NHS X.

COVID-19 Inquiry

20. Since the last meeting in July the HTA has been notified of a potential future contribution to the Covid Inquiry announced earlier this year. The HTA is awaiting further guidance on its contribution.

Finance

Table one: Financial position for Q2 2021/22

Human Tissue Authority

Summary Management Accounts for the six months ended 30 September 2021

	Actual	Budget	Variance	
	£	£	£	%
INCOME				
Grant in Aid	374,000	385,000	(11,000)	(2.86)
Non-cash cover	39,062	39,062	0	0
Licence Fee income	4,024,840	3,951,321	73,519	1.86
Devolved Governments	133,572	133,572	0	0
Other Income	25,128	25,129	(1)	0
TOTAL INCOME	**4,596,602**	**4,534,084**	**62,518**	**1.34**
OPERATING COSTS				
Staff costs (salaries etc)	1,575,782	1,618,264	(42,482)	(2.63)
Other staff costs (excl Inspections)	75,708	69,250	6,458	9.33
Board Costs	61,685	81,000	(19,315)	23.85
Inspection Costs	1,215	24,000	(22,785)	(94.94)
Living Organ Donation and Transplantation costs	318	7,000	(6,682)	(95.46)
Communication Costs	4,070	8,000	(3,930)	(49.13)
IT and Telecoms	172,139	187,500	(15,361)	(8.19)
Office and Administration Costs	13,662	57,895	(44,233)	(76.40)
Other costs	29,096	101,350	(72,254)	(71.29)
Legal and Professional	332,619	59,610	273,009	457.99
Accommodation costs	106,313	110,483	(4,171)	(3.77)
Non-cash costs	32,036	39,062	(7,026)	(17.99)
Total operating costs	**2,404,643**	**2,363,414**	**41,228**	**(5.98)**
Net Income/(expenditure)	**2,191,959**	**2,170,670**	**21,289**	**0.98**

21. Table one provides a summary of our financial position at the end of the second quarter of the 2021/22 business year. We are posting a slight surplus against our budgeted position of **£21k** before any adjustments. The components that make up our net position are described in more detail below (paragraphs 22 to 24).

Income

Table two: Income summary

Human Tissue Authority
Income Summary
For the six months ended 30 September 2021

	Actuals	Budget	Variance	
	£	£'	£	%
Grant in Aid	374,000	385,000	(11,000)	(2.86)
Non-cash	39,062	39,062	0	0
Sub-Total	**413,062**	**424,062**	**(11,000)**	**(2.86)**
Licence Fees				
Application Fees	54,810	0	54,810	0
Anatomy	112,430	109,880	2,550	2.32
Post-mortem	1,280,215	1,285,180	(4,965)	(0.39)
Public Display	20,035	20,360	(325)	(1.60)
Research	755,541	739,115	16,426	2.22
Human Application	1,484,683	1,486,426	(1,743)	(0.12)
ODT	317,125	310,360	6,765	2.18
Sub-Total	**4,024,840**	**3,951,321**	**73,519**	**1.86**
Other				
Secondees	25,128	25,129	(1)	(0.0)
Devolved Assemblies	133,572	133,572	0	0
Sub-Total	**158,700**	**158,701**	**(1)**	**0**
Total Income	**4,596,602**	**4,534,084**	**62,518**	**1.38**

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

- Grant in aid – is lower than budgeted due to a small variation in drawdown against the budget profiling.
- Licence fees – are above budget by **£54k**, which is due to application fees which are not budgeted for and the resulting licence fees for those new licences, mainly in the Research sector.
- Other income – is on budget.

Expenditure

23. **Staff costs (salaries)** – are under budget (£42.5k) due to vacancies across the organisation which are being recruited.

24. **Other staff costs (excl. inspection)** – are over budget by £6.5k. An overspend of £26k in recruitment costs, largely down to the recruitment of a new Chief executive, have been partially offset by underspends in training costs (£8k), staff travel costs (£6.5k) and staff benefits (£2k).

25. **Board costs** – include Member allowances, travel, and venue hire. The underspend (£19.3k) relates mainly to travel and venue costs as all meetings have been held virtually.

26. **Inspection costs** – as expected remain under budget as site visits have been suspended to the second half of the financial year due to the COVID-19 pandemic restrictions.

27. **Living Organ Donation, Transplantation and Communications costs** – are both under budget due to no in-person events or training and lower media monitoring costs, respectively.

28. **IT and Telecom costs** – as at the end of September we are under budget by £15k. This comprises an overspend in IT support and maintenance costs (£18k) which have been offset by underspends within IT consumables and telephone costs (£18k). Consultancy costs previously included (£15k) have been moved to the Development Program with a separate budget.

29**. Office and Administration costs** – are £44k under budget; this includes bad debts written off and other office administration costs which are all close to budget. The most significant variance is for the office relocation (£45k) which covers additional travel costs for staff which due to restrictions have not materialised.

30. **Other costs** – are under budget by £72k and is due to an underspend on the Website project which is one of the work packages for the Development Programme. We now anticipate these costs will occur later in the year and this budget will be re-profiled.

31. **Legal and professional costs** – are significantly over budget (£273k). Legal fees are over budget by £4k. In addition, we are overspending against our Consultancy costs (£243k) of which £230k relates to support to cover vacancies in our business planning roles.

32. **Accommodation costs** – are under budget by £4.2k. The underspend relates mainly to the rent and service charges for 2 Redman Place. The budget being based on figures provided in March. We have now signed the final Memorandum and Terms of Occupation (MOTO) with DHSC (Department of Health and Social Care) which included slightly more favourable changes to the HTA costs.

33. **Non-cash costs** – underspend of £7k represented by depreciation and amortisation costs of our tangible and intangible assets. This underspend will continue as the original budget was set prior to the major write-off of obsolete assets at the end of last year. These costs are provided for through "Ring-fenced RDEL" funding provided by the DHSC which we will reduce in future years.

Forecast outturn

34. We are currently forecasting a break-even position, and this will continue to be reviewed monthly.

Other key performance indicators

Debtors

35. At the end of September 2021, the total value of our debtors was **£2,653k** represented by **483** accounts. This is a significant reduction on the same period in 2020/21 where debts were £4,096k.

36. The table below gives a breakdown by sector.

Table three: Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	223	£1,575,365	59
Government Bodies	31	£230,355	9
Non-Government Bodies[1]	229	£847,306	32
Total	**483**	**£2,653,026**	**100**

37. Of the 223 NHS accounts, four (£4k) have been outstanding since the 2019/20 billing run and 13 (£83k) relate to the 2020/21 business year. We are in contact with each organisation and expect to clear these in this business year. The remaining 206 (£1,494) accounts are from the September 2021 licence fee invoice run.

38. Of the 31 Government Bodies, 28 (206k) have been invoiced as part of the September 2021 licence fee run.

39. Of the 229 Non-Government Bodies, 13 (£12k) relate to the 2019/20 and prior business year and six (£24k) to the 2020/21 year. As with the NHS organisations, we are actively pursuing these debts and expect resolution in 2021/22. There are eight (£75k) that relate to earlier in the current business year and a further 202 (£748k) just issued for the September licence fee invoice run.

People

COVID-19 response

40. All flexible working arrangements related to the pandemic have now been withdrawn to reflect the national guidelines and environment. However, staff are still encouraged to speak to their line managers or HR if they are experiencing any difficulty.

[1] Includes Universities and private organisations

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

New ways of working / Return to office-based working

42. The HTA continues to operate a default position of working from home. Access to the office in Stratford is available for those who wish to work from an office base. A small number of staff have started to attend once or twice a week on a regular basis.

Wellbeing

43. HTA continues to offer wellbeing support to staff who are working from home, however staff are being encouraged to look more widely at managing their wellbeing especially as we enter the winter months.

Recruitment and Retention

44. The recruitment programme is progressing well with 19 roles offered and accepted. A further four roles are in process.

Sickness absence

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

Pulse Survey

46. A Pulse survey was conducted in July. The response rate was below our usual 74 - 76% at 64%. However, there was a higher score on all of the six questions indicating that staff feel well informed and have a better understanding of what is expected of them. 96% said they feel connected to the work of the HTA compared to 86% in February 2021.

Equality, Diversity, and Inclusion

47. The HTA has adopted a strategic framework to facilitate and maintain good EDI (Equality Diversity and Inclusion) practice across the organisation that is also reflected in our systems and processes.

48. HTA-POL-009 Equality, Diversity and Human Rights Policy and HTA-POL-007 Recruitment, Induction, Probation and Secondment policy have both been reviewed and updated to reflect current best practice. Our recruitment practice has been to encourage and facilitate applications from a diverse pool of candidates with anonymised CV's and support for any adjustments through the recruitment process. This has been formalised in the policy.

49. We will continue to encourage staff to speak up about EDI matters or concerns formally via the HR policies, and informally via their line managers, through listening events and the Staff forum. We also encourage staff to feedback concerns via the Freedom to Speak Up Champion.

50. The HTA has promoted wider external EDI events such as Black History month, LGBT History month, Mental Health Awareness week in addition to highlighting events held by 'Race at Work.'

51. Previous Board discussions have noted the need for a cultural reset exercise. This has been discussed with the incoming CEO who will pick this work up early in the new year.

Freedom of Information requests

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

Complaints

53. In quarter two, no complaints were received by the HTA.

Latest review date – 04/10/2021

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	**12 - High**	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	**Suspended**		⇔⇔⇔⇔

* 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 18 months. Activity in the PM sector is now stable, with some emergency mortuary licences having been renewed. We are expecting a further expansion of licencing of funeral directors' premises to support national public health Covid surveillance. We have also dealt with around forty new import / export licences (or licence variations) in the HA sector because of licensing changes following EU Exit. We have adopted a proportionate approach to these new licences and SMT have agreed the longer-term regulatory approach to be adopted in relation to these new licences. At the start quarter 3 we have initiated a full schedule of regulatory assessments and site visits in line with pre-pandemic activity. 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 throughout the pandemic restrictions. We continue to actively manage a small number of regulatory matters with establishments SMT believes this risk is stable, at tolerance, in September 2021.

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	**4**	**3**	**12 -High**
Tolerance threshold:					**6 - Medium**

Commentary
At tolerance. This risk concerns our ability to respond to incidents irrespective of their nature or cause, which could be from matters outside the HTA's remit or control as well as matters for which we are directly responsible. The Executive has therefore set a lower tolerance level on this risk as our ability to respond appropriately is within the HTA's control. The HTA believes that our incident management response plans have been well tested and found to be robust and effective through their deployment in managing the impact of the pandemic and related restrictions and in their adaptation for use in managing the potential impacts of EU Exit following the end of the Transition Period. We have also used these arrangements more recently in preparing for the potential consequences of an incident which occurred at an establishment that, although not a regulatory matter, may lead to a significant impact on the HTA. Having increased the risk scoring in July we are of the opinion that the likelihood of this risk materialising remains high. Further clarity on the timelines for managing the confidential matter has been provided and we have put in place additional resource, both internal and external, to help manage this matter as it crystalises. We also note the likely continued demands on senior management in dealing with these matters and the stretch on the remaining members of the SMT with the departure of the CEO at the end of October 2021 SMT believe this risk remains high and although further mitigation actions and resources have been deployed that this will remain above tolerance for the next quarter.

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

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

Commentary
At tolerance. We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC (Department of Health and Social Care) and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit, but which may adversely impact on public confidence, is challenging. In 2020/21 the Development programme included a specific workstream to strengthen horizon scanning on emerging changes to policy and activities where the HTA may be required to act or offer an authoritative voice. This proactive approach went live in quarter four of 2020/21 and will continue to be embedded in 2021/22. 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. Work has also commenced to convene a round table discussion to address the issues associated with the use of tissue blocks and slides from coronial post-mortems for research, teaching and clinical audit. Work has continued to support the Public Health England initiated pilot project to undertake post-mortem surveillance sampling for COVID-19 through the licensing of Funeral Directors. The future demand for these licenses is currently uncertain and we are seeking further clarity on the next phase of the project. All these matters are being actively managed, and there has been no detrimental impact on the HTA's reputation. SMT believe this risk remains 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	**4**	**3**	**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. Key vacancies remain relating to the planning and portfolio manager, with plans for an interim appointment to be made during October, and with the pending departure of the Head of Business Technology in November 2021 recruitment for a replacement has commenced. The HTA's new Chief Executive, Dr Colin Sullivan, will begin his new role on 1 January 2022, with the current Chief Executive departing at the end of October plans have been agreed to distribute activities and responsibilities temporarily to other members of SMT. SMT believe that the risk tolerance has not changed and remains above tolerance, although significant progress has been made several vacancies gaps relating to planning and the pending departure of both the CEO and Head of Technology leave the organisation facing critical short-term pressures through quarters 3 and 4 of this business year. .

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. Planning for 2021/22 is now complete. DHSC has confirmed GIA (Grant in Aid) funding for the new financial year, and we expect additional funding for ongoing EU transition activities. With anticipated cost reductions from our estate, and the impact of ongoing restrictions on normal site visit and meetings/events likely to continue to reduce expenditure, we have allocated funds for the continuation of our development activities. As we approach the mid-year point our expenditure is in line with budgets and we forecast a balanced year end position whilst acknowledging some potential additional costs in relation to recruitment and specialist support. We expect the outcome of the 2021 Spending Review towards the end of the 2021 calendar year, we do not anticipate specific savings measures but are mindful that some small reductions in our Grant in Aid could be required. We expect to finalise recommendations on 2022/23 fees for the November Board meeting and subject to a settlement on GIA would expect to finalise budgets for 2022/23 and reach tolerance for this risk towards the end of Quarter 3.

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

Inherent risk level:			**Residual risk level:**		
Likelihood	Impact	Inherent risk	**Likelihood**	**Impact**	**Residual risk**
3	3	9 – Medium	**3**	**2**	**6- Medium**
Tolerance threshold:					**9 - Medium**

Commentary
At tolerance. As previously advised the risk has been suspended

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.

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.HTA 21a/21

Criteria for inclusion of risks

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

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

Rank

The risk summary is arranged in risk order.

Risk scoring system

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

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

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

Risk appetite and tolerance

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

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

Assessing inherent risk

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

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

Contingency actions

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

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

HTA 21b/21 Annex B - Strategic Risk Register 2021-22 - September

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, now being incorporated into business as usual. Development Programme-led activity from 2020/21 to develop a new Target Operating Model to re-state and clarify the key elements in our approach to regulation. 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 is aware of the risks and opportunities associated with the suspension of routine site visit inspections during Covid restrictions and how VRAs are being incorporated into BAU. Board aware of the issue of failing to meet the legal obligation to carry out a site visit of HA establishments at least once every two years because of the suspension of routine site visits during Covid. SMT agreed late May 2021 to resumption of routine site visits in HA sector once restrictions are lifted, alongside continuing use of VRAs. Continuing use of all other regulatory tools during the pandemic restrictions, including managing HTARIs and SAEARs, investigations, advice to regulated sectors (such as seminars in Anatomy sector, Professional Newsletters). Development and use of emergency mortuary licensing regime during the pandemic, including use of virtual assessment techniques. Development and use of funeral director licensing regime to support PHE-sponsored project of post-mortem public health surveillance for Covid-19.	In-depth evaluation of pilot programme of 10 x virtual regulatory assessments in the HA sector in quarter three 2020/21 carried out and reported to the HTA Board Meeting February 2021. VRAs being incorporated into BAU in HA sector from Quarter 4 2020/21, with plans to expand into all sectors during Quarters 1 and 2 or 2021/22, as evidenced in Business Plan. Internal Audit late Quarter 3 / early Quarter 4 2020/21 on 'Inspection Process during Covid-19' - draft report agreed late May 2021; Moderate assurance; to be considered by ARAC early June 2021. Renewal of emergency mortuary licences and expansion of Funeral Director licensing for removal of tissue for PHE post-mortem public health surveillance for Covid-19. Police referral made late 2019/20 being actively investigated by the police, with ongoing input (Witness Statements) from HTA.
						Regulatory decision making framework			Heads of Regulation using dashboards to track open cases and ensure there is effective follow-up, in accordance with the HTA's decision-making framework.		X			Preventative	Reports of key decisions in Board Reporting.	Satisfactory Internal Audit Report (strong assurance) November 2020. Lessons learned from Regulatory Decision Meetings (RDMs) held January 2020 and used to inform update to Regulatory Decision Making SOP. Regulatory Decision Making SOP updated February 2020. Evidence of regulatory decision making framework being used in practice 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	Latest update of HTA Strategy published November 2020. Annual Board Strategy session 27 April 2021 to consider annual strategy refresh.
						The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.			Following the departure of the Head of Planning and Performance, SMT and their Heads have ensured there is regular review and updating of the operational business plan and monthly performance pack. Plans to be put in place to re-introduce KPIs and PIs for internal decision making and external transparency and accountability.		X	X		Preventative	Operational business plan for 2021/22 (using Excel spreadsheet template developed in 2020/21) in use and reviewed regularly by SMT. Contractors engaged Quarter 1 2021/22 to support development of business planning through adoption of a portfolio management approach. 2020/21 narrative Business Plan was produced in Quarter 1 2020/21 and published during Quarter 2 (delayed by Covid). 2021/22 narrative Business Plan is currently under development.	Progress on the Portfolio Management approach being developed is a regular item of business at SMT meetings (most recently July 2021). SMT receives monthly reports of Management Information for review and action (most recently in July 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. Detailed evaluation carried out prior to adoption and expansion. Following Internal Audit on the Inspection Process during Covid, some further management actions are being undertaken, principally to ensure other regulatory processes and documentation (SOPs) are updated to take account of VRAs.			X	Detective	Internal audit conducted on Key Regulatory Processes late 2018/19, receiving substantial assurance and noting good areas of best practice. Internal audit on the Inspection Process during Covid-19 conducted late 2020/21 - see R4. Moderate assurance and management actions largely complete - to be considered by ARAC June 2021.	Final report received April 2019 and showed substantial assurance. The two low priority recommendations were followed-up with management actions completed during 2019/20, namely review of SOPs for key regulatory processes (completed) and training on core legislative framework, HT Act which was delivered in March 2020.
				Quality management systems								
				HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model		Following the departure of the Quality Manager in 2019/20, a Regulation Manager with experience in QMS has overseen and coordinated activities to ensure policies are reviewed and updated, with input and support from the Quality Forum as relevant.		X			Preventative/ Monitoring	Management oversight and reporting trough the monthly performance pack. This work is expected to transfer to a newly created role during Quarter 2 2021/22.	Limitations in QMS still remain. Scheduled reviews have now been re-instated following the departure of the quality manager with a schedule of activity in place. QMS and monthly performance reporting pack includes evidence of degree to which the documents are current.
				People								
				Adherence to the HTA People Strategy which has been substantially amended and approved by the Board				X			Preventative	Management information and assessment presented to the Board quarterly.	HR report included in Chief Executive's report to the Board at the July 2021 meeting. End-of-year reviews completed during Quarter 1 2021.
				Training and development of professional competence				X			Preventative	Annual PDPs, Corporate Training Programme (led by Head of HR), RM Training programme, Career Investment Scheme proposals to SMT	Evidence of corporate training programme, including quarterly mandatory training. Regulation-led Training sessions focusing on Change and VRAs. 'Lunch and Learn' programme.
				Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas		As vacancies arise, SMT take the opportunity to review business requirements and target building capability and filling skills gaps. An organisational redesign for aspects of the HTA's work was developed during late 2020/21 to enable key gaps and capability issues to be addressed and a large-scale recruitment programme for 10 posts, including the redesign, initiated in Quarter 1 of 2021/22.		X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur. Organisational design. Recruitment policy.	Staffing levels and risks reported quarterly to the Board 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 understanding item on SMT agenda. Internal Audit Quarter 3 of 2020/21 - moderate assurance. SMT lead for project - ANH (Director of Regulation). Formal project re-established from Quarter 3 2020/21. SMT papers for key decisions.	EU Exit - dedicated project manager (contractor) appointed Quarter 3 2020/21 until 31 July 2021. (Project due to be closed and handed over to business as usual by 31 July 2021.) EU Exit / UK Transition Project documentation and records in Teams Channel. Internal Audit on Risk focusing on EU Exit - reported January 2021, moderate assurance, completion of management actions tracked in audit tracker by ARAC. Standing item on SMT weekly minutes - EU Exit update - reported in minutes.
						Regulatory model						
						Development work being undertaken to become a more data-driven risk based regulator as part of the HTA Development Programme.		X			Preventative		
						Other						
						Strengthening horizon scanning arrangements		X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
2	***Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:*** • ***relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)*** • ***caused by deficiency in the HTA's regulation or operation*** • ***where we need to regulate, such as with emergency mortuaries*** • ***that causes business continuity issues*** ***(Risk to all Delivery Development and Deployment objectives)*** *Risk owner:* ***Nicky Harrison***	***Cause*** • *Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)* • *Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)* • *Failure to work effectively with partners/other organisations* • *Breach of data security* • *IT failure or attack incident affecting access to HTA office* • *External factors such as terrorist incident, large scale infrastructure failure or pandemic* ***Effect*** • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	***5***	***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***	***4***		***6***	X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020 Version 19 of CIRP published July 2019. CIRP deployed in March 2020 to manage coronavirus pandemic. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						All specific roles identified in the Critical Incident Response Plan are filled.					1 X	2	3	Preventative	Evidence of regular review and updating of the CIRP and no specific CIRP roles left vacant or, if role is vacant, cover arrangements put in place.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes. Business Continuity and Critical Incident Response Plans updated and approved by SMT on 10 June 2021.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.			Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media. Crisis comms consultants appointed and available to be used as required.		X			Preventative	Policy reviewed as scheduled. Reports on any key media issues and activity in the Chief Executive's Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the quarterly Board reporting as they arise and as relevant.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy			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. Engagement with NHS Counter Fraud Authority (CFA) on a matter where there appears to have been HTA regulatory breaches and offences as well as potential fraud offences, which NHS CFA are investigating.
						Onward delegation scheme and decision making framework agreed by the Board					X	X		Preventative	Standing Orders and Board minutes	Standing Orders published May 2017, due to be updated before Board meeting in 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.
						Evaluate test exercise of incident and feedback to all staff.			Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic.		X			Preventative	SMT content that activation and use of CIRP during first wave and first lockdown superseded the need for a test.	Noted in ARAC Audit Tracker.

					Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.		Awareness raised of PM sector reporting requirement (HTARIs) at external training events, e.g. 9 April 2021 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture, 18 September 2020 - Level 3 Diploma (Anatomical Pathology Technology) trainee APT HTA lecture Quarterly meeting with NHSBT to review ODT SAEARs cases over 90 days and any complex cases. Publication of quarterly incident numbers in the professional e-newsletter may remind establishments to report. HTA website COVID-19 guidance emphasizes 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		X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process. For example, as part of the current VRAs in the HA sector, we are specifically looking at each establishment's incident logs to check a) that they recoding incidents locally, and b) that incidents that should have been reported as SAEARs, were. Annual SARE (Serious Adverse Reactions and Events) HA SAEARs data reported to European Directorate for the Quality of Medicines (EDQM). Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups and advice, guidance and CAPAs regarding those incidents.	Findings at inspection (onsite or VRAs). Minutes of quarterly meeting with NHSBT to review SAEARs cases in ODT sector - latest meeting was 24 March 2021. Most recent SARE report submitted June 2020. Publication of closed SAEAR and HTARI incident summaries included in the HTA publication scheme - published quarterly - and reporting in the Board's data annex. Publication of incident numbers in the regular (bimonthly) Professional Newsletter.
					Management of any risk of incidents likely to arise from the end of the 6 months post-Transition Period grace period for EEA/GB import / export licensing continues to be managed through the defined UK Transition project. The Director of Regulation is SRO, with a dedicated project manager and project resource and close continuing engagement with DHSC.		Continuing engagement with DHSC on ongoing aspects of the UK Transition Period Project, including the Northern Ireland Protocol (and engagement with NI Executive Department of Health).					Preventative / Detective / Monitoring	Director-level oversight as SRO (Director of Regulation), weekly Project meetings, 'stand-up' over the 6 weeks either side of 31/12/20, regular reporting to SMT through standing agenda item and specific papers for key decisions.	Regular reports to SMT - standing item on SMT agenda from February 2020. Smooth management of the end of the transition period at 31/12/20 through the regular stand-ups (based on the CIRP) and project oversight. SMT paper 14 January agreed scope of next phase to 30 June 2021 with project closure expected by 31 July 2021. Internal Audit 2019/20 (Moderate assurance and most management actions completed by the end of May 2021). Rapid replacement of contractor project manager following departure of former incumbent to ensure continued rigour in approach to project management.

HTA 21b/21 Annex B - Strategic Risk Register 2021-22 - September

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK I	INHERENT RISK L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
3	**Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach** **(Risk to Delivery objective e, and Development c)** *Risk Owner:* ***Louise Dineley***	***Cause*** ***External factors*** • *No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)* • *Rapidly advancing life sciences* • *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates* • *Introduction of deemed consent for Organ donation in England* • *Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario* ***Matters which certain stakeholder groups believe require review*** • *Scope of relevant material e.g. waste products* • *Licensing requirements e.g. transplantation research* • *Regulation relating to child bone marrow donors* • *Issues raised by emergence of social media e.g. non-related donors* • *Strengthening of civil sanctions for non-compliance* ***Matters which stakeholders/public may expect to be inside regulatory scope*** • *Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure* • *Police holdings* • *Products of conception and fetal remains* • *Data generated from human tissue* • *Funeral directors* • *Forensic research facilities* • *Cryonics* • *Body stores / Taphonomy* • *Imported material* • *Clinical waste* • ***Other*** • *Inadequate stakeholder management* ***Effect*** • *Diminished professional confidence in the adequacy of the legislation* • *Reduced public confidence in regulation of matters relating to human tissue* • *Reputational damage*	*5*	*4*	*Ongoing*	Horizon scanning process in place that creates and maintains an up to date log of issues known to the HTA with respect to the legislation (updates, amendments or emerging issues) to inform DH and manage messages	*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 May 2019.* *Professional newsletters issued regularly - last one May 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 July 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 20211 re Quarter 1 2021/22.*
						Action where we believe it will support public confidence					*X*			*Preventative*	*Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance also published. These publications reflect the importance of ongoing publications and updates to specific conditions.*	Update to the Board and DHSC at Board meeting July 2021. Professional newsletter May 2021.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge			*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.*
						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.

					Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for key pressures such as ongoing response to Covid-19; winter pressures, Transition Period and the period after 31 December 2020. In the last 6 months the HTA has demonstrated its role in strategic and partnership working as part of the wider Life Sciences & regulatory system and has demonstrated a responsiveness to legislative amendments and updates.		*Ongoing engagement with partner organisations to build opportunities for collaboration and support to the life sciences sector.*		x			*Preventative*	*Development programme workstream Strengthening of Horizon scanning has identified 4 areas to progress in 2021/22.*	*Regular reporting to SMT and through formal routes*

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	Risk Tolerance	LINE OF DEFENCE 1	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**	3	4	*All major projects have project management rigour further enhanced through benefits realisation and plans to assess ROI at year end.*	9	1	2	3			
						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 program me 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 focusing 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.
						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 May 2021
						Licence fee modelling								Preventative	Annual update to fees model	No change to fees agreed by the Board November 2020 meeting
						Rigorous debt recovery procedure					X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Level of 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	Will go 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 July 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.

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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							1	2	3			
						SMT experience of organisational change, programme and project management.	2	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:	04 November 2021
Paper reference:	HTA 21c/21 (Board Supplementary Data Annex)
Agenda item:	06
Author:	Nicolette Harrison Director of Regulation

OFFICIAL

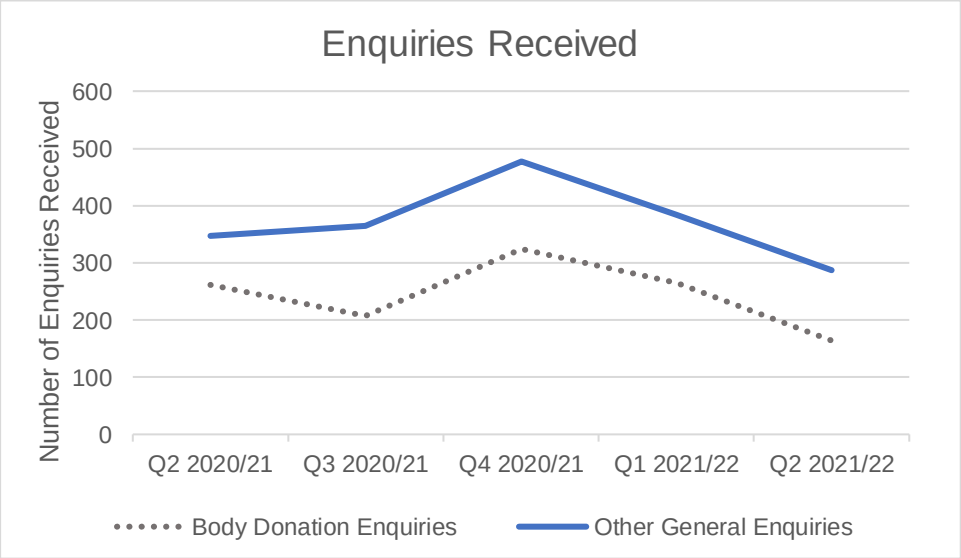
Purpose of Report

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

Enquiries

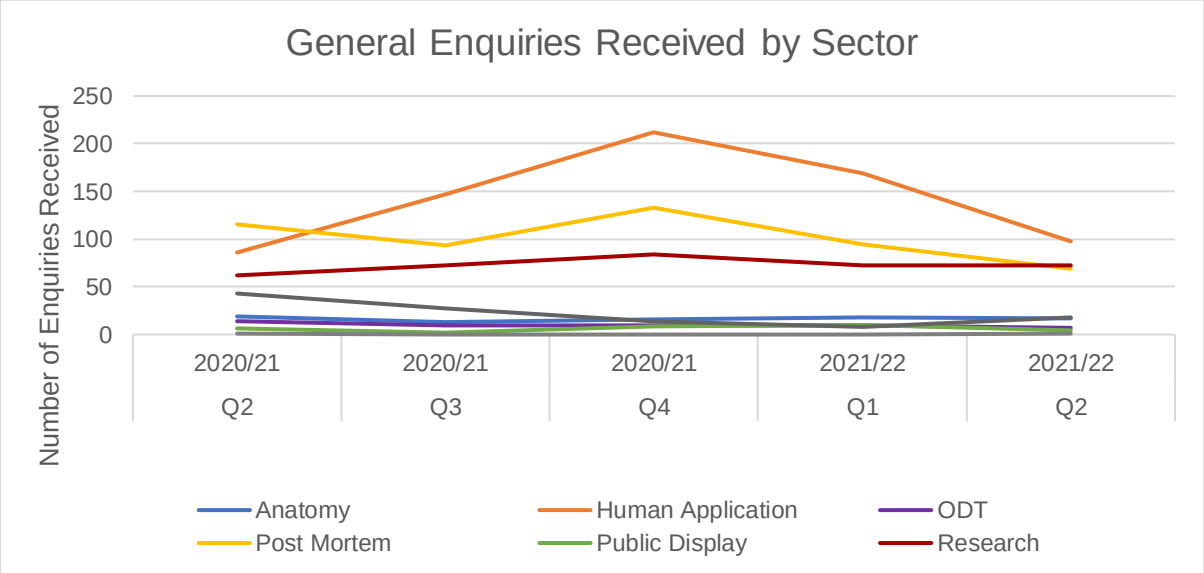
2. Figure 1 below displays the total number of body donation enquiries and other general enquiries received. 287 general enquiries and 164 body donation enquiries were received.

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



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

Figure 2: General Enquiries Received by sector (excluding Body Donation Enquiries)



Licensing

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

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

Sector	New Licence Application	No. of Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	1	1	0	0	0
Human Application	8	7	3	0	0
Organ Donation and Transplantation	0	0	0	0	0
Post-Mortem	1	1	0	0	0
Public Display	0	0	0	0	0
Research	4	4	4	1	0
Total	14	13	7	1	0

5. 14 new licence applications were received in quarter two. For comparison, in 2020/21 we received ten applications per quarter on average.

6. Eight applications were received in the Human Application sector, four applications in the Research sector, one in the Anatomy sector and one in the Post-mortem sector.

7. Decisions were made on 13 applications, of which all 13 were granted (seven in the Human Application sector, one in the Post-Mortem sector, four in the Research sector and one in the Anatomy sector).

8. There were seven satellite additions (three in the Human Application sector and four in the Post-Mortem sector).

9. One revocation took place in the Research sector.

Licensing Variations

10. Figure 3 displays the total number of licensing variations received each quarter. A total of 203 licensing variations were received in quarter two.

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

Figure 3: Total number of licensing variations received each quarter

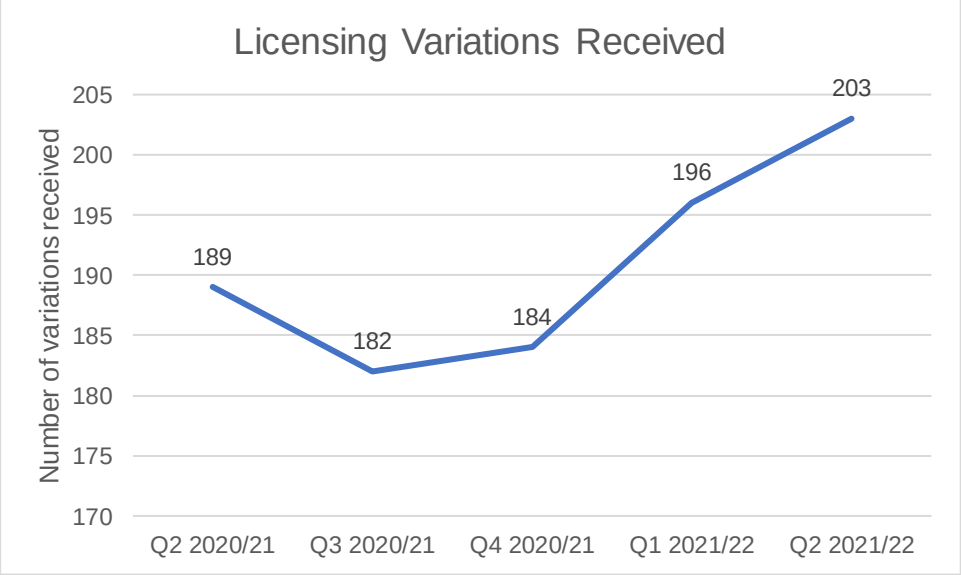
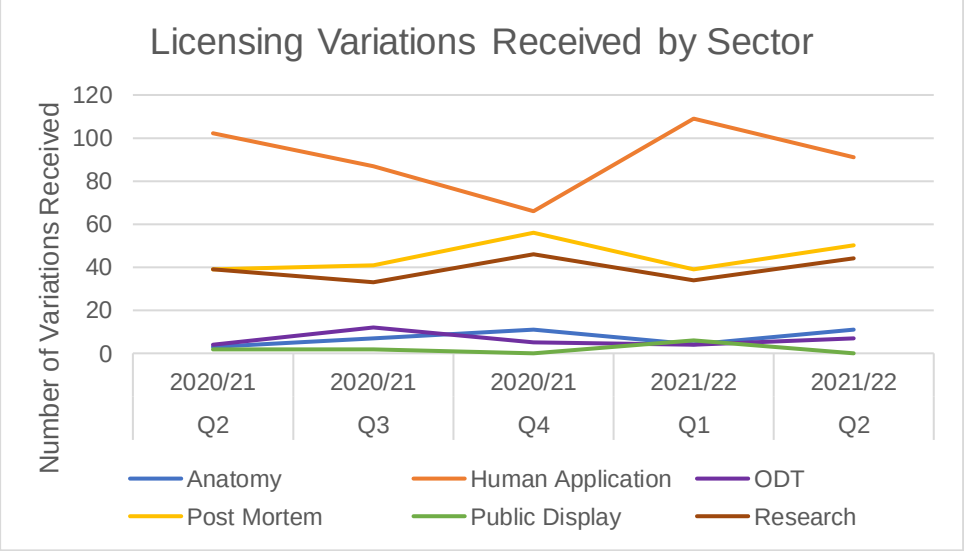


Figure 4: Total number of licensing variations by sector

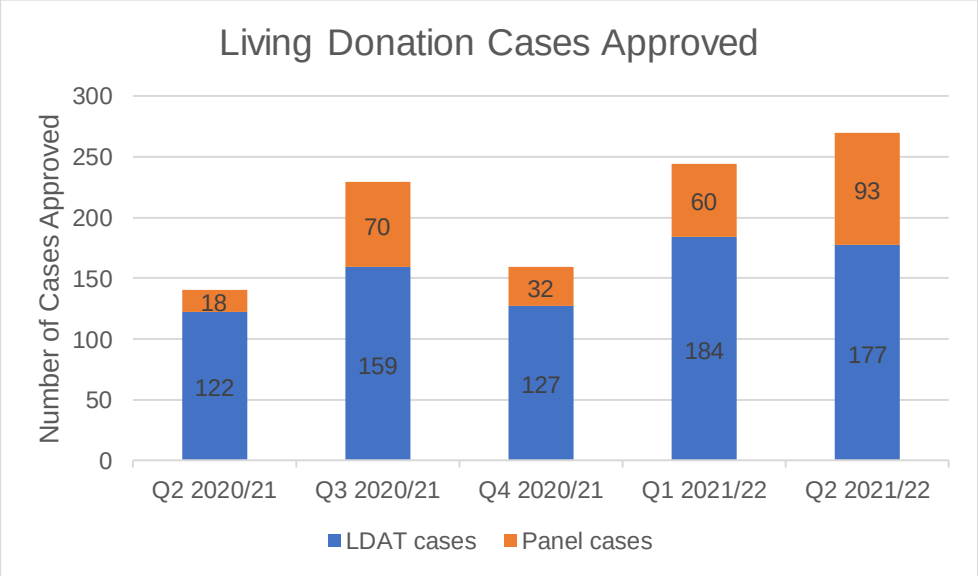


Living Donation

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

13. In quarter two, 177 cases were approved by the LDAT and 93 cases were approved by panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 5: Number of living donation cases approved per quarter



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

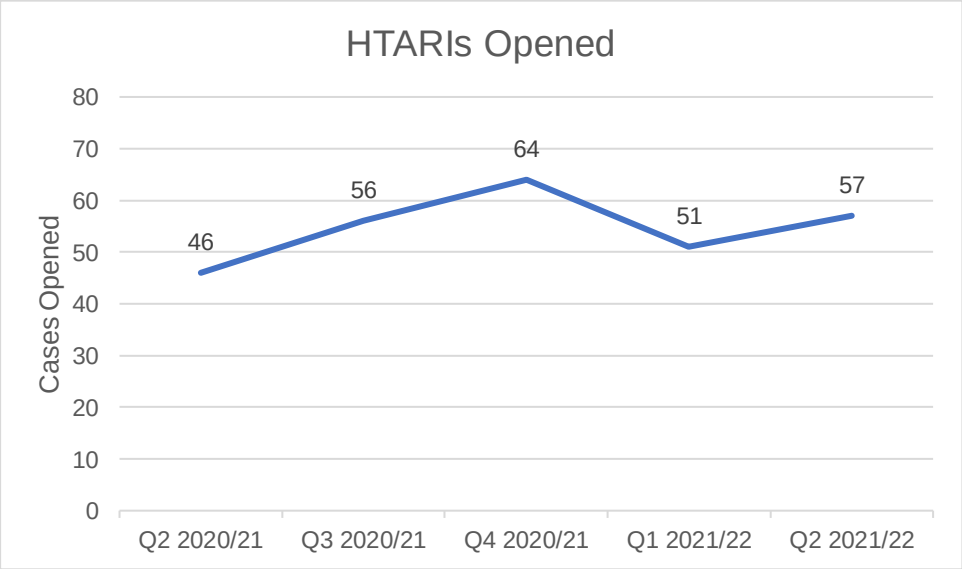
Table 2: Total number of bone marrow and PBSC cases approved

	Q2 2020/21	Q3 2020/21	Q4 2020/21	Q1 2021/22	Q2 2021/22	2019/20 Total	2020/21 Total
Bone Marrow/PBSC Cases Approved	15	17	14	12	8	66	62

Incidents – HTA Reportable Incidents (HTARIs)

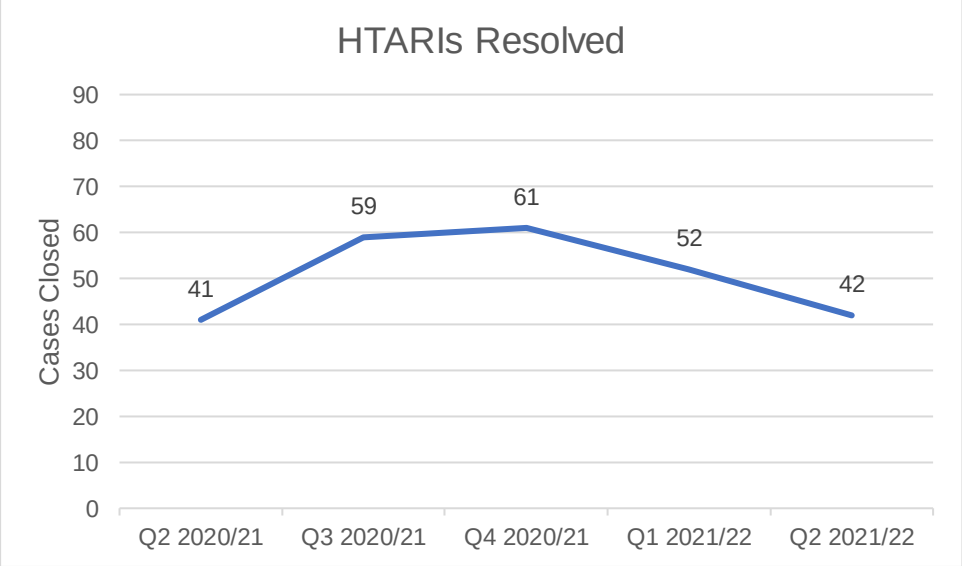
15. Figure 6 displays the number of reported HTARIs in quarter two compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. In quarter two, 57 HTARI cases were opened, compared to 51 cases opened in the previous quarter.

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



16. Figure 7 displays the number of HTARIs resolved in quarter two compared to preceding quarters. 42 HTARIs were resolved in quarter two, compared to 52 resolved in the previous quarter.

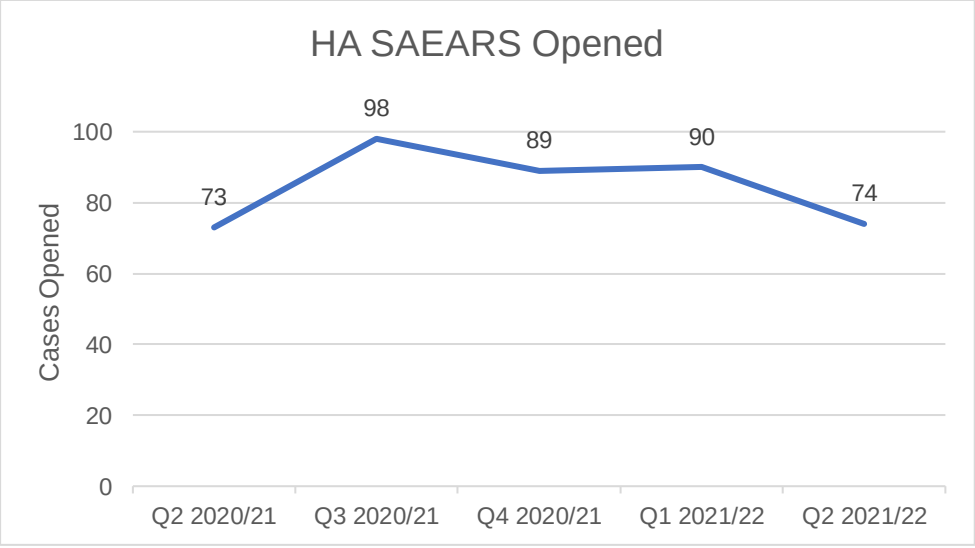
Figure 7: HTARI cases resolved during quarter in the Post Mortem sector



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

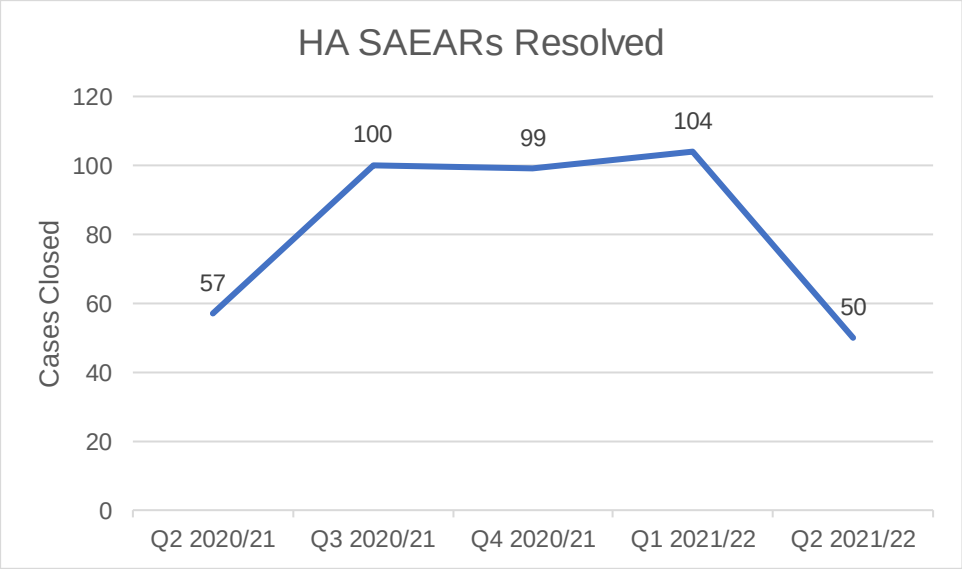
17. Figure 8 below displays the number of reported HA SAEARs in quarter two compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR. In quarter two, 74 HA SAEARs cases were opened, compared to 90 cases opened in the previous quarter.

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



18. Figure 9 displays the number of HA SAEARs resolved in quarter two compared to preceding quarters. 50 HA SAEARs cases were resolved in quarter two, compared to 104 cases resolved in quarter four.

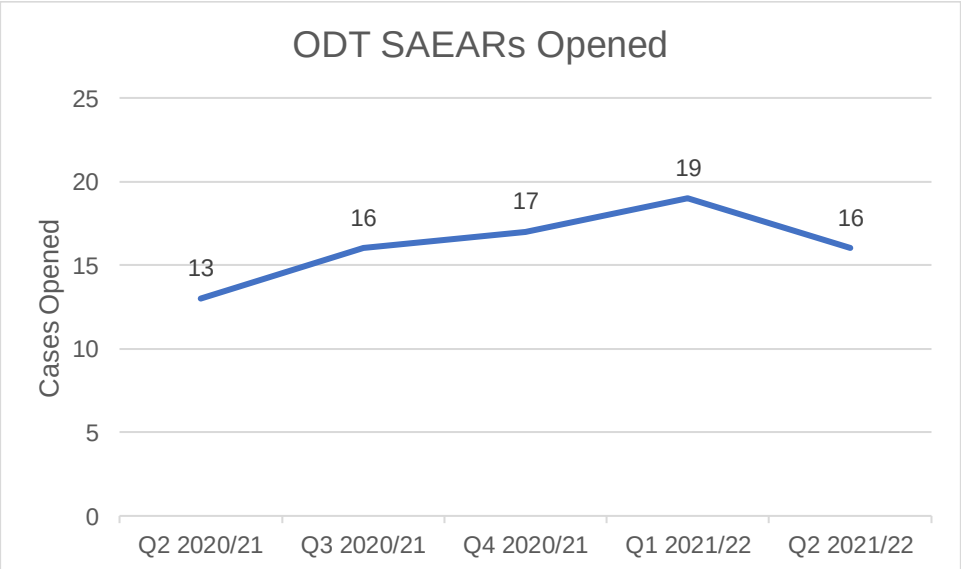
Figure 9: SAEARs resolved during quarter two in the Human Application sector



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

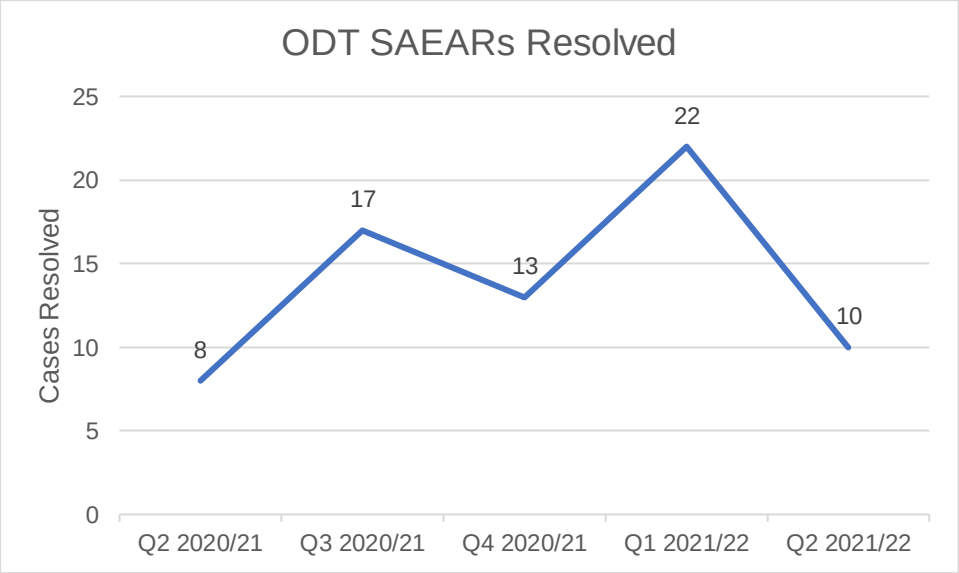
19. Figure 10 below displays the number of reported ODT SAEARs in quarter two compared to preceding quarters. In quarter two, 16 ODT SAEARs cases were opened, compared to 19 cases opened in the previous quarter.

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



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

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



Corrective and Preventative Action Plans (CAPAs)

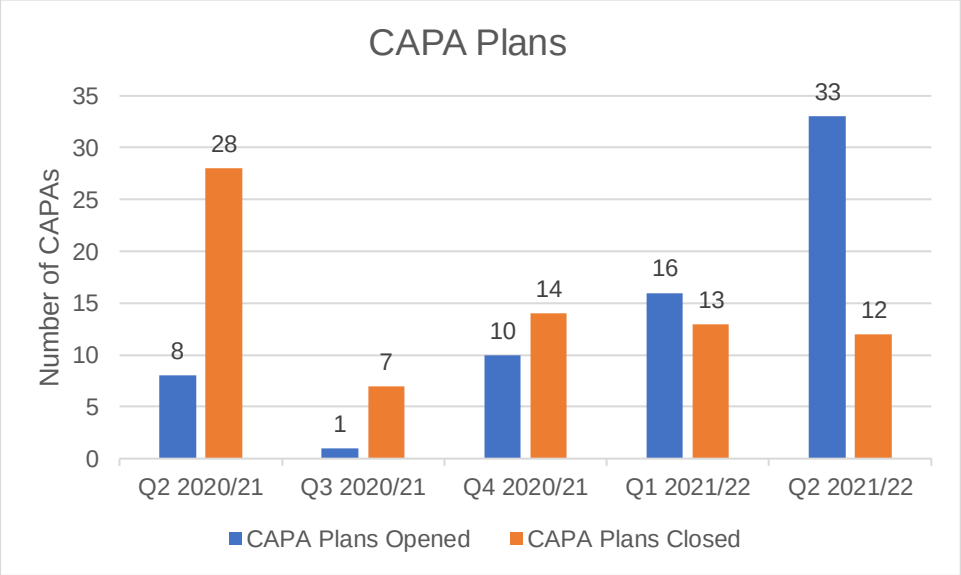
21. Figure 12 displays the number of CAPA (Corrective and Preventative Action Plans) plans opened and closed during quarter two, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered, and investigations.

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

23. A total of 33 new CAPA plans were opened in quarter two. This includes 21 opened in the Human Application sector, eight opened in the Post-Mortem sector and four opened in the Research sector.

24. A total of 12 CAPA plans were closed in quarter two. This includes six in the Human Application sector, two in the Post-Mortem sector and four in the Research sector.

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



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

26. There was a total of 41 CAPA plans open at the end of quarter two. 34 CAPA plans have been open for less than six months and seven CAPA plans have been open for longer than 12 months.

Table 3: All Open CAPA plans

Open CAPA Plans	Anatomy	Post-Mortem	Human Application	Research	Public Display	ODT	Total
< 6 months	0	7	25	2	0	0	34
6-12 months	0	0	0	0	0	0	0
> 12 months	0	1	6	0	0	0	7
Total	0	8	31	2	0	0	41

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 22/21

Agenda item: 07

Author: Richard Sydee
Director of Resources

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 14 October 2021.

Decision Making

2. The SMT approved this paper for presentation to the Board on 21 October 2021.

Action required

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

Background

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

Internal Audit

5. The Committee noted two reports from the 2021/22 audit plan. These covered a finding of substantial assurance from an audit undertaken of the HTA approach to staff wellbeing on which the committee congratulated management and the HTA's HR team. The second report was a finding of limited assurance relating to the evidence that underpinned the HTA's submission of the NHS Digital Data Security and Protection Toolkit (DSPT).

6. The Committee acknowledged that this was the HTA's first submission of the DSPT and that it did not in isolation, represent any identified weakness in the HTA's data and cyber security approach. It welcomed the commitment to undertake further work to strengthen the evidential base for the next submission due in June 2022.

7. The Committee noted the amended audit plan for the business year 2021/22 and the significant progress that had been made in clearing audit recommendations.

External Audit

8. The National Audit Office engagement Director for the HTA, Mike Surman, outlined the intention of the NAO to contract out the HTA audit for the next three years to one of their external partners. Dean Gibbs, Audit Director at KPMG, was introduced as the lead for the HTA's external audit for 2021/22, he outlined the preparatory work already undertaken and plans for further work over the coming weeks. The Committee thanked Mike and Dean for their explanation of the process and work to make this transition as smooth as possible. The Committee also welcomed confirmation that the proposed audit team would be in place for the next few years.

Strategic Risk Register

9. The Committee discussed the strategic risk register in some detail. It was noted that a full site visit and assessment plan was now in place for the second half of the business year and the Committee noted the positive impact this will have on the HTA's ability to regulate appropriately.

10. The Committee noted the continued above tolerance status of Risk 2 - *failure to manage an incident* and acknowledged the unprecedented demands that a

number of regulatory matters was placing on the senior management team. Risks 3, 5 and 6 were all noted.

11. The Committee then undertook a deep dive review of risk 4 - *failure to utilise capabilities effectively*. The Committee noted the work undertaken to improve both the systems and processes that support the work of the HTA and acknowledged the improvements in technology that had been implemented. The recent recruitment activity and difficulties in recruiting to certain posts were noted by the Committee, it welcomed the progress on recruiting a replacement for the Head of Business Technology and the plans that have been agreed to manage the HTA between October 2021 and January 2022 ahead of the new Chief Executive taking up post.

Other items

12. The Committee received an update on Cyber Security from the HTA's Head of Business Technology, and requested further improvements to the dashboard to further improve the assurance provided by this report. It also noted an update on the HTA's development programme

13. The Committee reviewed revisions to the HTA's Counter Fraud, Bribery and Corruption strategy, noting the recommendations of the DHSC (Department of Health and Social Care) Anti-Fraud unit to strengthen the approach, and the Reserves policy. Finally, the Committee noted that an undocumented artwork that had been displayed at the HTA's previous office has been gifted to the Government Arts Collection, with a deed of gift having been signed on behalf of the HTA by the Director of Resources.

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 23/21

Agenda item: 08

Author: Louise Dineley
Director of Data, Technology and Development

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Development Programme Update

Purpose of paper

1. The purpose of this paper is to provide the Board with:
    a. A look back over the quarter of progress against the Programme plan.
    b. A forward look at Programme deliverables in the next quarter.
    c. A series of scenarios that supports flexibility and the reprioritisation of resources to business activities.

Action required

2. The Board is asked to:
    a. Note the update on the quarter two deliverables.
    b. Note the deliverables for quarter three and the factors that may impact on these.

Background

3. There are three priority projects in 2021/22. These are:
   - The establishment and adoption of an Enterprise Content Management System.
   - The development of the HTA's data and intelligence systems and future capability to adopt a more risk-based approach to oversight and regulatory action.
   - The implementation of a Target Operating Model.

   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 in 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.

4. In parallel to the HTA's Development Programme we have continued to contribute to a number of external projects over the last quarter. These have included Data Collaboration Partnership and the development and progress of the Life Sciences vision working with other regulators and Arms Length Bodies.

Quarter two 2021/22 – update on deliverables

5. The deliverables for the three priority projects and the programme overall in the quarter are outlined below with a RAG rated assessment of achievement.

6. *Completion of "as is" and "to be" business process mapping including data flows to support and inform future system and data architecture.*
   Status: AMBER

   The business process mapping of the "as is" and "to be" has not been completed in quarter 2. The revised commission set in August failed to deliver to the requirements set for the Development Programme. Key gaps included the omission of data flows, a lack of consistency in the level of mapping with no high-level map at the domain level produced and missed or incomplete processes. A recovery plan is in place to complete the mapping of the "as is" by the end of the

quarter. The plan for delivery of the "to be" maps has been reframed and extended into early quarter three.

7. *Development and roll out of a data collection pilot and a test version of the Regulatory Insight Model and Index (RIMI)*
Status: AMBER

   There is a critical dependency between the data flow mapping and the data collection pilot. The delay in the production of the data flow maps is having a knock-on effect on the design and roll out of the data collection pilot. To mitigate the impact, we have reviewed additional actions that can replicate, in part, the pilot. These actions include the implementation of the proof-of concept model developed last year, the development of a revised, updated set of data indicators (to be tested) and plans for an initial engagement event with external stakeholders.

8. *Develop the transition architecture for the Enterprise Content Management System to be built in quarter three*
Status: AMBER

   Collection of the business requirements for the transition architecture has commenced with the aim of a draft specification produced by the end of the quarter. This draft specification will be used to engage developer resource for the design and development of the architecture. The output of the transition architecture has been reframed as an early quarter three deliverable due to the dependency with the "to be" output.

9. *Agree and commence targeted developments of the Target Operating Model*
Status: GREEN

   Over the last quarter the Operating Model has evolved to provide a vision for a Target Operating Model (TOM) including opportunities for improvements and developments. The draft TOM will be used as the basis of the "to be" mapping with opportunities for improvements signed off via the SMT (Senior Management Team) as initial priorities and future opportunities assessed against resource investment and benefits to be realised.

10. *A first draft of future workforce requirements to inform wider organisational preparedness and the options to develop or access core skill sets.*
    Status: AMBER / GREEN

    As projects progress, we have considered the impact of any change or development on the current and future skills required from the HTA workforce. In conjunction with the Head of HR, these skills requirements are being collected and added to the skills mapping tool.

11. In addition to the above actions, work has also progressed to support the organisation and its preparedness for the future changes and development. The appointment of a Change Manager has provided an opportunity to focus on the embedding of developments and changes in ways of working implemented in the last 12 months. This embedding will in part be evaluative and reflective of intended use of systems and benefits realised.

Quarter Three 2021/22 Deliverables

12. By the end of quarter three we aim to have delivered:
    - An updated version of the Regulatory Insight & Index Model (RIMI).
    - The design phase of the transition architecture of ECMS.
    - 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.
    - Future workforce skills map to inform workforce development and future operating model.
    - Engagement with stakeholders (internal and external).

13. The planned deliverables in quarter three will be kept under review to take into account changes to staffing and corporate priorities. The current plan reflects a slowing down in the pace of change which will inevitably impact on the overall ambition of change and benefits to be achieved in 2021/22.

14. As part of the planning, three scenarios have been considered. These are:

    Scenario 1: Continued delivery of the Development Programme as planned in 2021/22. The risk of this scenario is that engagement and collaboration internally

may be limited based on the availability of resources outside of the Development Programme project team. Resource capacity will be stretched which has a potential knock-on effect on other projects including business as usual activities.

Scenario 2: The deliverables and ambition of the Development Programme are adjusted for 2021/22. This scenario involves a conscious pause of certain projects, a slowing of pace on activities and also an active decision not to prioritise internal resource deployment to development and change activities. The risk associated with this scenario is that the required strategic development of regulatory models, systems, processes, and the benefits associated with these changes will be delayed into 2022/23.

Scenario 3: The Development Programme and individual projects are recognised as priorities within the overall planning of business activities and allocation of resources. This scenario requires all HTA activities to be actively considered in terms of relative priority and resource allocation. The portfolio management approach that would support this is evolving and whilst offering strategic principles to support SMT, decision making is embryonic in operational delivery.

15. At the time of this report scenario 2 is being worked to, although it is hoped as quarter three progresses, scenario 3 may offer an opportunity to recover.

Governance & Leadership

16. The governance of the Development Programme was set out at the beginning of this year. This includes a fortnight project team, monthly reporting to the Director of Data, Technology & Development, and a monthly update report to SMT with suggested areas of greater focus. In quarter three SMT will be seeking to explore and progress themes identified in quarter two covering people, processes, and systems.

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 24/21

Agenda item: 9

Author: Richard Sydee – Director of Resources

OFFICIAL

HTA Fees - proposals for 2022/23

Purpose of paper

1. This paper recommends the budget to be recovered from licensed sectors and the licence fee structure for 2022/23.

Action

2. The Board is asked to agree:

    a) the total HTA budget of £5.04m.
    b) the proposal to increase fees for 2022/23 and increase overall fee recovery.

Decision-making process to date

3. At its meeting on 21 October 2021, SMT (Senior Management Team) agreed a proposal to increase HTA fees by 1% for the 2022/23 financial year. **This paper has since been updated to reflect details released as part of the Autumn Budget announcement.**

Background

4. The HTA charges fees to fund regulatory activities. The costs of regulating each sector are funded by fees from each sector, including a suitable proportion of overheads. Other HTA costs, such as work associated with living organ donation and some overheads are funded by Grant-in-aid from the Department of Health and Social Care (DHSC).

5. The HTA's fees model allocates the amount the HTA needs to recover across sectors and different licence types. It uses information about the number and profile of establishments in each sector, (in normal circumstance) how many site visits we plan to make and how many other activities might arise in each sector. It also incorporates estimates of how other areas of regulatory activity and support fall across all sectors.

Fee income required

6. As part of setting our budget for the 2022/23 financial year SMT discussed the emerging financial pressures on the HTA. We note that the preferred inflation indicator, CPIH, is currently at 2.9 % (September 2021); however, this is not indicative of the pressures facing the HTA for the upcoming financial year and we have incorporated the following material points in setting a budget for the 2022/23:

    - Our budget assumes a full staff complement for the 2022/23 financial year.

    - Overall staff costs represent c80% of HTA's annual expenditure and is therefore our most significant pressure. Given the freeze on public sector pay increases during 2021 there has been limited upward pressure on overall pay costs. **The announcement of the lifting of the public sector pay freeze from 1 April 2022 was made after this paper was considered by SMT. Although this will allow the HTA to make staff a pay award from August 2022 the parameters of this award are unlikely to be announced until the new calendar year.**

    - Recent appointments have placed an upward pressure on our staffing budget of c1%. Additional Employers National Insurance contributions, which commence in April 2022, are expected to be funded by HM Treasury for public sector organisations.

- We expect Grant in Aid (GIA) from the Department of Health and Social Care to remain at the level received from 2021/22. We do not anticipate confirmation of this until December 2021.

- We have budgeted for the continuation of our re-established site visit programme and for Board and Committee meetings to return to some in person meetings from the start of the 2022/23 financial year.

- Other potential areas of cost increase, relating to wider inflationary pressures on external venues, travel, and accommodation, have been considered but have minimal impact on our overall budget given the limited expenditure compared to staff costs

7. The proposed baseline budget for 2022/23, before allowing for a pay award in August 2022, is therefore slightly increased, up c 1% from £4.99m to £5.04m, to reflect the pressures listed above.

8. The baseline budget excludes wider ambitions relating to our technology development programme or any wider strategic ambitions the Board may identify in the coming months.

9. SMT have considered the possibility of:
   - freezing fees for the second consecutive year, therefore needing to find some internal savings or efficiencies to offset the inflationary pressures identified;
   - increasing fees by 1% or 2% to recognise the known inflationary pressures; or,
   - increasing fees by CPIH, to reflect both the known inflationary pressures and to provide funds to further advance the strategic objectives of the HTA as set by the Board.

10. The fees that would be chargeable under all options (current Fees, 1%, 2% and a CPIH increase) are set out in Annex A to this paper.

Recommended Fee levels

11. It is **recommended** that the Human Tissue Authority increase fees by at least 1%, the impact across all sectors is set out in detail at Annex A.

12. Although acknowledging the current CPI rate it was felt that an increase at or above this rate could not be justified given the “real” inflationary pressure faced by the HTA for 2022/23. With known inflationary pressures of 1%, and the potential to make a pay award to staff, the Board may consider a 2% increase in fees to be appropriate.

13. On balance SMT agreed that it was appropriate to increase fees, given that efficiency savings have previously been passed on to stakeholders through the freeze on fees for the 2021/22 financial year.

14. SMT have also proposed 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.

Next steps

15. The Board is asked to consider the proposed fee increases for 2022/23. We aim to publish these fees on our website for all stakeholders in December 2021.

Annex A. HTA License Fees – Current and Increased by 1%, 2% and 3%

Public Display	Current	1%	2%	3%
Main fee	£1,315	£1,328	£1,341	£1,354
Each of satellites 1-4	£325	£328	£332	£335
Each of satellites 5+	£165	£167	£168	£170

Organ Donation and Transplantation	Current	1%	2%	3%
Main fee	£4,225	£4,267	£4,310	£4,352
Plus 1-2 organ types				
Fee level 1	£3,155	£3,187	£3,218	£3,250
Plus 3 organ types				
Fee level 2	£6,295	£6,358	£6,421	£6,484
Plus 4 organ types				
Fee level 3	£8,385	£8,469	£8,553	£8,637
Plus 5+ organ types				
Fee level 4	£10,400	£10,504	£10,608	£10,712
Organisation responsible for procuring organs	£30,215	£30,517	£30,819	£31,121

Post-Mortem	Current	1%	2%	3%
Main fee	£3,420	£3,454	£3,488	£3,523
PM examination – Main Site	£2,405	£2,429	£2,453	£2,477
PM examination – Satellite	£1,200	£1,212	£1,224	£1,236
Storage	£345	£348	£352	£355
Removal for a scheduled purpose	£345	£348	£352	£355
Each of satellite 1-4	£1,550	£1,566	£1,581	£1,597
Each of satellite 5+	£805	£813	£821	£829

Research	Current	1%	2%	3%
Main fee	£3,530	£3,565	£3,601	£0
Each of satellite 1-4	£835	£843	£852	£860
Each of satellite 5+	£420	£424	£428	£433

Anatomy	Current	1%	2%	3%

Main fee	£2,550	£2,576	£2,601	£2,627
Each of satellites 1-4	£410	£414	£418	£422
Each of satellites 5+	£205	£207	£209	£211

Human Application	Current	1%	2%	3%
Main fee	£5,720	£5,777	£5,834	£5,892
5+ tissue types	£2,030	£2,050	£2,071	£2,091
Processing	£3,045	£3,075	£3,106	£3,136
Procurement	£1,070	£1,081	£1,091	£1,102
Testing	£1,070	£1,081	£1,091	£1,102
Storage	£1,070	£1,081	£1,091	£1,102
Distribution	£540	£545	£551	£556
Import	£1,070	£1,081	£1,091	£1,102
Export	£540	£545	£551	£556
Each of satellite 1-4	£3,640	£3,676	£3,713	£3,749
Each of satellite 5+	£2,030	£2,050	£2,071	£2,091

Application Fees

Fees	Current	1%	2%	3%
All sectors excluding Human Application				
Main site	£3,225	£3,257	£3,290	£3,322
Satellite	£825	£833	£842	£850
Human Application				
Main site	£4,160	£4,202	£4,243	£4,285
Satellite	£885	£894	£903	£912

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 25/21

Agenda item: 10

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

OFFICIAL

Living Donation Update - 12-month review of recommendation process

Purpose of paper

1. The purpose of this paper is to provide members with an update 12 months after implementing the new process for cases requiring decision by a Panel.

Decision-making to date

2. This paper was approved by SMT (Senior Management Team) on 21 October 2021.

Action required

3. Members are asked to note and comment on this paper.

Background

4. In July 2020, members were provided with a proposal for a new way of assessing cases requiring Panel decision. This was with the aim of reducing the amount of time members were spending reviewing cases. It was agreed this process should be trialled.

5. At the Board meeting in November 2020, members provided feedback on the new process. It was noted that the trial period had provided sufficient evidence to suggest that the new approach was working well. Full detail of cases remained available for review if required. The Board were asked to consider whether the case assessment timescales could be reduced from ten to five working days.

6. At that stage, the Board did not feel they could consider reducing the assessment target and it was agreed this should remain at ten working days.

7. The Board agreed that the new approach should be rolled out on a permanent basis, with a review in 12 months' time. It was also suggested that a quality assurance mechanism should be developed and implemented.

8. This paper provides the Board with a 12-month post implementation review. Information regarding the quality assurance mechanism is also included.

12-month update

9. In the period 1 November 2020 to 30 September 2021, a total of 227 cases requiring Panel decision were assessed.

10. The table below shows the breakdown, by category, of cases considered by Panel during this period:

Donation category and assessment timeframe	**Number of cases reviewed by Panel**
Non-Directed Altruistic Donation	61
Paired/Pooled Donation	165

Directed Donation (this case potentially involved an element of economic dependence)	1
Percentage of cases where decision made within five days or less	75% (170 cases)
Percentage of cases where decision made within six to 10 days	25% (57 cases)

Quality assurance mechanism

11. A quality assurance mechanism has been developed to ensure the recommendations presented to Panel members provide high quality, accurate information to enable each Panel to fulfil their statutory duty.

12. Quarterly quality assurance checks have been carried out by the Transplant Manager (TM) on 20% of all Panel cases received. The Head of Regulation (HoR) has carried out two quality assurance checks, in March 2021 and August 2021, on a sample of 5% of all Panel cases received.

13. Cases were chosen at random to ensure fairness. Recommendations completed by both Transplant Officers (TOs) and the TM were reviewed meaning that recommendations completed by all members of the Living Organ Donation (LOD) team have been quality checked.

Quality assurance results

14. A summary of the quality assurance results, and a sample of comments from members on the quality of the recommendations, can be found at Annex A.

15. Overall, the quality checks confirmed that recommendations made to the Panel are of a good standard and ensure that the key facts needed to assess the case are included. Nonetheless, some areas of improvement have been identified.

    - There is a need for members of the LOD team to check their recommendation for typographical errors before the case is assigned to the Panel. This includes ensuring that information in the IA report such as spelling of the donor/recipient names, and dates of birth are correct. An

addition has been made to the recommendation template to ensure this is the final step to be performed before the recommendation can be considered complete.

- In a small number of cases, some additional detail in places would have been helpful. However, all cases were found to contain sufficient information on which to base a decision.

- On one occasion, a Panel member noted that the recommendation attached to the case was for another case. Whilst this was an isolated incident, the team have adopted more rigorous checks before cases are assigned. This includes re-checking the detail of the recommendation against the IA report.

16. From 1 November 2021 quality assurance checks will be performed on a monthly basis to support learning for all LOD team members and to reduce the number of recommendations where simple typographical errors are made.

17. A reminder has also been added to check whether any additional detail from the report should be included that may add value and assist the Panel.

18. A collective team review of one recommendation will be undertaken every month to ensure all LOD team members have a common understanding of the detail that should be included in the recommendation.

Feedback from Board Members

19. We have received positive verbal feedback from members confirming that the recommendation has helped reduce the time it takes to assess cases. On average, reviewing the recommendation and writing comments on the case is estimated to take between 10-15 minutes.

20. Some members continue to review all documentation available to them, including the Independent Assessor (IA) report. We welcome any suggestions for further improvements that could be made to the recommendation document, however members will continue to have access to all supporting documentation.

Timeframes for case assessment

21. During the period 1 November 2020 – 30 September 2021, due to requests from transplant centres for shorter turnarounds, 35 Panel cases required a decision in fewer than ten working days. This accounted for 15% of Panel cases.

22. Of the 35 cases requiring a shorter turnaround, 19 of these were Non-Directed Altruistic donation cases. These cases require HTA approval before a donor can be registered and entered into the Living Kidney Sharing Scheme.

23. 75% of Panel cases received between 1 November 2020 and 30 September 2021 were approved by Panel within five working days.

Points for consideration for the future

24. At the Board Meeting in November 2020, Members were asked to consider whether they would support the case assessment timescales being reduced from ten to five working days.

25. Whilst we are not proposing to change the timeframe for case assessment at this time, we recommend that this is kept under review and may need to be revisited.

26. The Living Kidney Sharing Scheme is recovering but living donation numbers have not recovered in the same way as deceased donation numbers. Some NHS Blood and Transplant (NHSBT) matching runs were suspended during the worst of the pandemic. The impact of this has meant extended waiting times for donors and recipients and the creation of large and complex matching runs for NHSBT colleagues to manage. This has led to an increase in Panel cases over recent months. As a result, the LOD team has experienced a rise in the number of transplant centres seeking assurance that decisions on Panel cases will be provided as quickly as possible. The additional pressure at the current time is due, in part, to the number of living donation transplant surgeries postponed due to Covid-19.

27. The newly published NHSBT strategy *Organ Donation and Transplantation 2030: Meeting the Need* sets out seven actions in relation to living donation, the first of which is to “maximise transplant opportunities in the UK through the

Living Kidney Sharing Scheme." We can therefore reasonably expect to see an increase in the number of cases requiring Panel decision, alongside continued requests for shorter turnarounds on cases from transplant centres facilitating these logistically challenging surgeries.

28. A recent consultation held by the Department for Business, Energy and Industrial Strategy was about *Reforming the framework for better regulation* in the UK, with a strong focus on proportionality. The consultation was clear on the need for regulators to continue to adapt and evolve the way we regulate. In addition, one of the eight priority areas for action resulting from the *'Busting Bureaucracy' consultation* held by Department of Health and Social Care in 2020 was that "system and professional regulation will be proportionate and intelligent."

29. The vast majority of Panel cases are now considered to be routine and are no longer new. There is a strong argument therefore for the Regulations to be revisited to remove the requirement for these cases to be referred to Panel, which no longer feels proportionate.

30. It is not likely that any such review will take place in the immediate future. As such, it is important to recognise that in response to the NHSBT aim to maximise the use of the Living Kidney Sharing Scheme, it is likely that we may need to revisit the possibility of reducing the assessment target for Panel cases from ten to five working days.

Next steps

31. The Board is asked to consider and note the information included within this paper.

Annex A

Summary of quality assurance check results.

Quality check	Number of cases checked	Overall quality score	Areas of improvement required	Feedback provided by HoR or TM
December 2020 - TM	9	Good recommendation, with thorough detail in most places.	A discrepancy in the date of birth of a donor was noted by the Panel that the LOD team member had missed – feedback was provided to the team to ensure name and date of birth are cross-checked thoroughly. A Panel member had requested the LOD team to seek clarification on some aspects of the donor's understanding of the paired/pooled process.	The team were reminded to ensure name and date of birth are cross-checked thoroughly. The team were reminded to ensure the necessary clarifications are sought prior to submitting recommendation.
March 2021 - TM	7	Good recommendation, with appropriate	It was noted some areas of the template that	The team were reminded to ensure final

		detail in most places.	act as a guide to the LOD team were not deleted from the recommendation before attaching to the case. There were also instances where some further detail may have been useful to the Panel when making a decision on the case, however sufficient information was provided for each recommendation that was checked.	checks for spelling and presentation of the recommendation document are carried out before attaching it to the case. A discussion was held to ensure all team members understood the level of detail required and what additional information may be useful to Panel.
March 2021 – HoR check	6	Good recommendations with sufficient information included some cases included greater detail.	Some typographical errors.	A discussion was held to remind team to include spell check before attaching to case.
June 2021 - TM	12	Good recommendations including appropriate detail		Team were reminded to consider adding

		to provide background to Panel.		detail on a case-by-case basis.
August 2021 - HoR	5	Good recommendations including relevant detail to provide background to Panel.	Typographical errors – donor was referred to as female in places and was male. A donors first name and surname had been entered the wrong way round in IA report and this was not identified. Some further detail could have been included in one case which would have helped the Panel's decision. Please note: Outside of the quality assurance checks, in August a Board Member had	The feedback was shared amongst the team to remind the importance of final checks. The team discussed what detail would be good when providing recommendations to ensure that the Panel had a good background of the case. The team recognised the need to ensure final checks were made before

			highlighted the incorrect recommendation had been attached to a case.	assigning the case. A note has been added to the recommendation template to remind LOD team members to check the recommendation is the correct one.
September 2021 - TM	18	Good recommendations including examples of good detail to provide background to Panel.	A few cases where the recommendation still included the prompts for user i.e., not deleting the 'delete if not applicable' where the case is paired/pooled, and section refers to non-directed altruistic. A Panel member also noted that in a case involving kidney donation, the pre-filled prompt including the word 'liver' was not deleted from the recommendation	Team had joint discussion about the reminders being there for the teams use only and should be deleted before finalising recommendation for Panel. This was noted by the team, the additional final reminder to check the recommendation before it is attached to the case will help prevent this from

				happening going forward.

Feedback from Members in relation to the quality of the recommendation template. These comments have been taken from cases referred to Panel.

Month	Feedback
December 2020	'I have reviewed the recommendation document provided and note that there is a good amount of detail included.'
April 2021	'I have reviewed the detailed HTA recommendation and helpful additional comments therein.'
April 2021	'The additional information included within the recommendation that has been gained from conversations with the LDC at the referring unit and the IA are most helpful, allaying any possible concerns in respect of the donor's medical history.'
May 2021	'The Summary Report is fulsome on the issues of duress, coercion and reward and there are no contra-indicators. I am content to approve this application.'
May 2021	'LODT Case Summary Report is sufficiently expansive to provide the necessary assurance that the prospective donor has consented freely and knows that he can change his mind.'
July 2021	'The recommendation provides assurance the donor has a good understanding of the scheme, procedure and associated risks for her personally, and that there is no evidence of duress, coercion or reward.'

Human Tissue Authority
Board meeting

Date: 04 November 2021

Paper reference: HTA 26/21

Agenda item: 11

Author: Nicolette Harrison - Director of Regulation

OFFICIAL

Police Referral Policy

Purpose of paper

1. The purpose of this paper is for the Board to note the changes to the HTA's Police Referral Policy.

Decision making to date

2. The substantive proposed changes (highlighted in yellow) were discussed and agreed by HTA's Senior Management Team (SMT) at its meeting on 9 July 2020, with some further minor factual amendments (highlighted in green) agreed by SMT on 28 October 2021.

3. SMT noted they would report these amendments to the policy to the Board.

Action required

4. A copy of the revised Police Referral Policy, as approved by the SMT, is annexed to this report.

5. The HTA Board is invited to note the HTA's updated Police Referral Policy, in which all changes made have been highlighted.

Background

6. The HTA has a policy to manage referring alleged breaches of the Human Tissue Act to the police for further investigation and any potential prosecution.

7. This process was used in making a referral to the police in Spring 2020, for an investigation that has been taken forward by the relevant Police force.

8. In light of the experience of implementing the policy, some changes were agreed to the Policy. The substantive proposed changes (highlighted in yellow) were discussed and agreed by HTA's Senior Management Team (SMT) at its meeting on 9 July 2020, with some further minor factual amendments (highlighted in green) agreed by SMT in October 2021.

HTA26a/21 Annex Police Referral Policy Document

Policy for managing and referring potential criminal breaches of Human Tissue legislation

Version	17.3	**Last reviewed on**	9 February 2017
Reference number	HTA-POL-023	**Next review due**	On next use
Author(s)	Allan Marriott Smith	**Owner**	CEO
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 warrant under the Human Tissue Act 2004.

3. When we refer to Human Tissue legislation we mean:

   a) the Human Tissue Act 2004 ("the Act"),
   b) the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("the 2007 Regulations"), and
   c) the Quality and Safety of Organs Intended for Transplantation Regulations 2012 ("the 2012 Regulations")

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

Background

5. Human tissue legislation sets out the activities that have the potential to become 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;
    - through HTA powers to issue Directions e.g. non-consensual DNA analysis.

    Other activities will remain 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 appeared to have been committed.

8. This policy relates only to the management and referral of potential offences committed in England, Wales and Northern Ireland. Where the HTA identifies potential offences carried out in Scotland[1], police referral will be made via the appropriate Scottish Government officials.

Legal Considerations relevant to the HTA's role

9. 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

[1] The HTA may identify potential offences committed in Scotland in its role as UK Competent Authority under European legislation. It may also identify offences in the course of making living donation assessments, which the HTA undertakes under contract to the Scottish Government.

Authority has to determine what its role should be. In making that decision, the following factors have been taken into account.

- A person duly authorised by the Authority and by signed warrant has power to search any premises (not only licensed premises) where there are reasonable grounds to believe that an offence is being or has been committed. Such 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 an offence. This suggests that the Authority may have a role to play in gathering evidence to support investigation of a potential criminal offence referred to the police by either the HTA or other parties.
- The Authority is given no express power under the Act to conduct interviews under caution. Although the absence of an express power does not prevent members of staff of the Authority conducting interviews under caution, the Authority takes the view that the absence of express provisions in the legislation points against assuming that role in relation to criminal investigations.
- 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.

10. Some of the offences under the Act require the consent of the Director of Public Prosecutions ("the DPP") in order to prosecute. For practical reasons, the involvement of the Crown Prosecution Service (CPS) would be required in relation to such offences.

11. 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 CPS.

12. In making a decision about referral to the police for investigation, the HTA considers the impact that any offence, and its severity, has on patient safety (see indicative factors in para 28). The CPS, in deciding whether or not to bring a prosecution, will consider whether doing so is in the public interest. As a result, it is at the discretion of the CPS whether or not to bring a prosecution in a situation where there is evidence of an offence having been committed under human tissue legislation. This position is consistent with the HTA's duty to superintend compliance with its founding legislation (see para 13).

13. 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

14. 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.

15. 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. However, 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 irrationally or without consideration of relevant factors or after taking into account irrelevant factors. Decision-making, therefore, needs to be properly reasoned and documented. A decision not to refer may be revisited if circumstances suggest that further review is appropriate.

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 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 a list of indicative factors.

17. In adopting this 'indicative factors' approach for decisions on whether to refer a case to the police for investigation and potential prosecution under the Act, or Regulations, lists of factors have been established which may point in favour of or against referral.

18. The absence of relevant evidence should not necessarily be a reason which prevents the Authority from making a referral as, in many cases, the referral to

the police will be for the purpose of investigating whether there is evidence of an offence.

HTA decision making process

19. The HTA's decision making framework sets out the principles of decision making within the HTA and the delegation of decision making for possible police referrals.

Notification of potential offence

20. 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

21. 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 SMT.

22. 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 of this is 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 be a criminal offence, and/or one which can be managed using regulatory tools. The Director of Regulation will inform the CEO of the potential criminal offence at the earliest opportunity.

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

24. 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.

25. 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

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

27. 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.

28. 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.

Indicative factors in deciding whether to refer to the police

Factors in favour of referral

29. The following may be regarded as 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 that 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, 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

Factors against referral

30. The following may be regarded as 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
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

31. 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

32. 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.

33. Any personal data processed by the implementation of this policy will be done so in accordance with the HTA's Privacy Notice.

Process for referral to the police

34. SMT will delegate responsibility for making the police referral to the appropriate Head who will liaise with ~~the~~ Home Office or national police contacts to identify the appropriate point of contact within the relevant police force. 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 ~~regulatory~~ investigation ~~report~~ 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 checklist 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

35. 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 referral may be made orally with the full paperwork provided subsequently.

36. 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.

37. Section 5 (consent), section 32 (commercial dealings in transplantation) and section 33 (restrictions on living organ donation) of the HT Act 2004 include offences that require the consent of the DPP for prosecution. Where the HTA becomes aware of this type of alleged offence, the HTA will alert the CPS in each of these cases at the same time a referral is made to the police. Given that there will be few opportunities for individual police forces to develop any expertise in relation to Human Tissue legislation; the HTA will ensure that at the time of any such referral, the ~~Special Crime Division of the~~ CPS~~Crown Prosecution Service~~ is notified.

38. During an investigation, the police may require formal statements from HTA members of staff or other types of information. These will be requested through the appropriate Head at the HTA.

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

Authorisation of the police to obtain and execute a warrant

40. 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 HT Act 2004. 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").

41. There are multiple references to a "duly authorised person" in Schedule 5 of the HT Act 2004 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, and it is evident that the legislators intentionally opted not to limit the "person" in this way.

42. The Criminal Justice and Police Act 2001 has been amended to very clearly refer to parts of Schedule 5 of the HT Act 2004 and clearly anticipates that the police may be involved in the seizure and retention of material under this Schedule.

43. Paragraph 3 of Schedule 5 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.

44. 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 (entry and search in connection with suspected offence) and who is executing a warrant issued under that paragraph, as the "investigator".

45. 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), 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) of inspection and seizure of property;
    e) a description of the requirement under paragraph 5(5) 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), to bring with him such other persons and equipment as he considers necessary;
        ii. under paragraph 6(2), 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) 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 if—
        i. he fails without reasonable excuse to comply with a requirement under paragraph 6(3), or
        ii. he intentionally obstructs the exercise of any right under Schedule 5.

46. 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, legal advice has recommended that there is a formal written document, letter of appointment or similar which makes clear the person who is "duly authorised" by the Authority for the purposes of paragraph 3 of Schedule 5 to the Act (entry and search in connection with suspected offence). The duly authorised person should have this document with them on any search.

47. 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 B. The application will require "sworn information" that there are reasonable grounds for believing that (a) that an offence under Part 1 or 2 or under the Human Transplantation (Wales) Act 2013 is being, or has been, committed on any premises, and (b) that any of the conditions in sub-paragraph (2) is 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 might want to collaborate in relation to the sworn information and a sworn statement could be prepared by a senior member of the Authority (the Director of Regulation) if necessary but this is not a requirement of the legislation and it might be done by an investigating police officer.

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 HT Act 2004 and the HTA Entry and Search Regulations. There is a requirement under paragraph 7 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, give him a copy of the report.

51. Under section 21 of Schedule 2 of the HT Act 2004, 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, the Onward Delegation Scheme of the HTA's Standing Orders set outs that 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 HT Act 2004.

53. Following a decision to duly authorise, a letter of appointment should be prepared - which confirms the name/s of the person (or persons) being authorised and in relation to which 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, ~~January 2013~~ October 2018) ~~https://www.cps.gov.uk/publications/docs/code_2013_accessible_english.pdf~~ https://www.cps.gov.uk/publication/code-crown-prosecutors	Last accessed ~~7 October 2016 25 June 2020~~ 15 October 2021
~~Guidance booklet for Experts (ACPO and CPS, May 2010)~~ ~~http://www.cps.gov.uk/legal/assets/uploads/files/Guidance_for_Experts_-_2010_edition.pdf~~ Guidance for Experts on Disclosure, Unused Material and Case Management (CPS, September 2019) https://www.cps.gov.uk/legal-guidance/cps-guidance-experts-disclosure-unused-material-and-case-management	Last accessed ~~7 October 2016 25 June 2020~~ 15 October 2021

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 on 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 combined amends of versions 17.2 and 17.3 approved by HTA Board [DMY]

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 envisages the prosecution of individuals and 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.

4. An offence can also be committed by neglect.

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

5. In addition to offences created by the Act, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (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.

Offences under the Quality and Safety of Organs Intended for Transplantation Regulations 2012

6. Offences under the 2012 Regulations 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.