HTA
Human Tissue Authority

Ninety-third Meeting of the Human Tissue Authority

Date   16 July 2020
Time   10.00 – 12.10
Venue Via Zoom

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 7 May 2020 meeting	HTA (13/20)
4.	Matters arising from 7 May 2020 meeting	HTA (14/20)
	Regular Reporting	
5.	Chair's Report	Oral
6.	Chief Executive's Report	HTA (15/20)
	Strategic Risk Register	HTA (15a/20)
	Business Continuity	
7.	Business Continuity- Regulatory Update	HTA (16/20)
	Supplementary Data Annex	HTA (16a/20)
8.	Business Continuity- Development Programme	HTA (17/20)
	Committees/Working Groups	
9.	Audit and Risk Assurance Committee Update	HTA (18/20)
	Policy Updates	
10.	Professional Stakeholder Evaluation	HTA (19/20)
11.	Living Donation Policy Issues	HTA (20/20)
	Any Other Business	
12.	Any Other Business	Oral
	Close	

Minutes of the ninety-second meeting of the Human Tissue Authority

Date	7 May 2020
Venue	Zoom meeting
Protective Marking	OFFICIAL

Present	
Members	**In attendance**
Lynne Berry (HTA Chair) Dr. Stuart Dollow Amanda Gibbon Prof. Andrew (Andy) Hall William (Bill) Horne Glenn Houston Prof. Penney Lewis Bishop Graham Usher Dr. Lorna Williamson, OBE Prof. Anthony Warrens Prof. Gary Crowe Dr. Hossam Abdalla Dr. Charmaine Griffiths	Allan Marriott-Smith (Chief Executive) Richard Sydee (Director of Resources) Louise Dineley, (Director of Data, Technology and Development) Amy Thomas (Head of Development) Nima Sharma (Board Secretary; minute taking)
	Observers
	Jacky Cooper, Department of Health and Social Care (DHSC)
Apologies	
Nicolette (Nicky) Harrison, Director of Regulation	

Item	Title	Action
Item 1	**Welcome and apologies**	
	1. The Chair welcomed Members, attendees and observers to the ninety-second meeting of the Board of the Human Tissue Authority (HTA).	
	2. The Chair welcomed Jacky Cooper to the meeting and noted an apology from Nicky Harrison.	

Item 2	**Declarations of Interest**	
	3. The Chair asked Members to declare any personal or pecuniary interests that they may have in relation to this meeting's agenda. 4. There was one declaration of interest made by Dr Charmaine Griffiths in relation to the British Heart Foundation's active support for deemed consent for organ donation. This was noted by the Board.	
Item 3	**Minutes of 6 February 2020 meeting [HTA 07/20]**	
	5. The Chair requested Members' comments on the minutes for factual accuracy. Dr Hossam Abdalla requested that the minutes from the previous meeting are amended to indicate that he was absent from the November meeting due to illness. There were no further comments made. 6. The Board approved the minutes.	
Item 4	**Matters Arising from 7 November and 18 July 2019 Meeting [08/20]**	
	7. The Chair noted that all actions from the last meeting on 6 February 2020 were complete. 8. The Chair noted that actions from 18 July 2019 and 7 November 2019 were ongoing and referred Members to the matters arising log. The Board noted that some of these actions would be discussed at the July meeting. 9. The Board asked for an update on recruitment to the Quality Governance Manager and Business Analyst roles. Allan Marriott-Smith informed the Board that the Executive had decided to delay the recruitment to these roles at present. The Board was informed that various functions of these roles were currently being undertaken by existing members of staff. 10. The Board noted the content of this item.	
Item 5	**Chair's Report [Oral]**	
	11. The Chair provided an update on two key areas; Stakeholder meetings and Board appointments.	

	12. The Chair informed the Board that Ministers had decided not to extend the terms of those Members whose terms of appointment end in the autumn for a further year. The process for recruiting new Members would commence shortly, and brief extensions may be possible if appointments are not made by the time current Members' terms end.	
	13. The Chair highlighted that the Board would be informed more fully about HTA committee membership in due course but in the mean time reiterated that Professor Gary Crowe would take on the role as Chair of Audit and Risk Assurance Committee (ARAC) from October 2020.	
	14. The Board discussed the importance of having sufficent Board Members in place to facilitate the assessment of living donation cases, which are expected to increase over time once the pandemic eases. The Board agreed that it is important to consider the risks to the approvals system if there are fewer Board Members available to consider cases.	
	15. The Board noted the content of this update.	
Item 6	**Chief Executive's Report [HTA 09/20]**	
	16. Allan Marriott-Smith presented this item and introduced the report.	
	17. Allan provided the Board with an overview of the report which includes details on the successful progress of development projects in the last quarter of the year, including the introduction of the HTA intranet which has been a great step forward for internal communications.	
	18. Richard Sydee provided a summary of the financial outturn position at year end and highlighted an anticipated underspend of £19,000 (subject to audit). The Board was informed that the auditors were in the process of completing their work and that there were no concerns highlighted over the HTA's accounts for the financial year 2019/20.	
	19. The Board had a number of questions surrounding the report which were answered during the meeting.	

- Queries were raised about whether licensed establishments are requesting deferral of licence fee payments as a result of COVID-19. The Board was informed that the HTA had not received any formal requests to revoke licences and all billing would be delayed until September 2020.

- Members commented that Board costs appear to be quite high relative to the overall cost. The Board was informed that these costs also include Member remuneration. Members requested that future reporting should include a separate breakdown of Board salary costs and travel and subsistence costs.

20. Allan highlighted the particular importance of staff well being in the current operating circumstances and noted the management focus on this. During the meeting Allan presented results from a short pulse survey. The results provided some evidence that staff are coping well and feel well informed about the forward plans. Amanda Gibbon commended the results and confirmed that this interpretation was corroborated by the Chair of the HTA Staff Forum.

21. Board Members were informed that a new move date for the planned move to Stratford would need to be confirmed by early 2021 and that the HTA would be able to occupy the current offices until March 2021.

22. Louise Dineley provided Members with a summary of the two data annexes included as part of the Chief Executive's report. Members requested a more focussed analysis to be undertaken on HTA Reportable Incidents (HTARIs) and Serious Adverse Events and Reactions (SAEARs) to help the HTA to understand the potential indicators of risk and, in turn, maintain oversight of the relevant sectors.

23. The Board questioned whether there was any change in the nature of HTARIs, in particular, being reported to the HTA as a result of COVID-19 and the set up of emergency mortuaries. The Board was informed that there was no change in the nature of incidents reported to the HTA.

24. The Board highlighted their concerns about the increasing number of SAEARs identified over the last few years. Louise informed the Board that she would clarify these issues

	internally. A fuller account would be provided to the July Board meeting.	
	25. The Board noted the content of this report.	
	Action 1: Nicky Harrison to provide a fuller account of trends in SAEARs at the July Board meeting and thereafter.	**ANH**
Item 7	**Business Continuity- Risks and Issues [HTA 10/20]**	
	26. Allan Marriott-Smith presented this item to the Board.	
	27. Members were asked to note that only the first page of the strategic risk register was included. Allan highlighted that the pressure on risks, one, three and four were upward for quarter four.	
	28. The Board queried whether the Regulation Manager- Training role would continue. The Board was informed that it would not continue and should a need arise in the future the HTA would revisit the role.	
	29. The Board also questioned whether there had been a reduction in staff capacity due to the COVID-19 pandemic. Allan confirmed that there was currently no impact on staff directly, but, highlighted that there were a number of staff who had caring and childcare responsibilities and a number who had suffered bereavements.	
	30. The Board agreed that the eventual return to office working would need to be carefully considered by the Senior Management Team (SMT) taking into consideration preferences staff may have or other demands required of them, such as caring responsibilities. The Board also acknowledged that it would be critical to establish how social distancing could be maintained in the work environment.	
	31. The Board commended the SMT and HTA staff on their response to managing the COVID-19 crisis as well as all their efforts in ensuring a smooth transition to the current way of working.	
	32. The Board noted the content of this paper.	

Item 8	Business Continuity Regulatory Response [HTA 11/20]	
	33. Allan Marriott-Smith presented this paper to the Board and Dr Robert Watson joined the meeting for this item to provide additional support in answering specific questions.	6
	34. The Board was informed that the HTA had stood down inspections for quarters one and two across all sectors and that there remained a legal obligation to inspect every two years in the Human Application (HA) sector.	
	35. The HTA was currently reviewing the risk profile of each HA establishment. The HTA would need to consider other mechanisms with which to satisy itself that standards continue to be met. At present the Executive is considering how desk based assessment could be developed to fulfil this role.	
	36. The Board asked whether any feedback from European colleagues on how they have dealt with this had been sought. The Board was informed that it is difficult to benchmark with equivalent organisations outside the UK but some regulatory bodies in both the UK and in Europe do not inspect as regularly as the HTA.	
	37. The Board noted that public confidence in mortuaries was a critical issue and that under the current circumstances the HTA would need to consider a full assessment of risks of non-compliance in this sector. The Executive informed the Board that all ideas were welcome on risk-based analysis and that the Board's views would be sought to develop an approach to managing regulatory risk in the absence of inspection.	
	38. The Board emphasised the importance of the HTA considering the perceived risks and public expectation of any regulator during the pandemic and whether the HTA could coordinate its management of risk with similar regulators to understand their approach to this. Allan informed the Board that he was having regular meetings with the Human Fertilisation and Embryology Authority (HFEA) and Health Research Authority (HRA) to ensure that each regulator was taking a co-ordinated approach.	
	39. The Board noted the content of this paper.	

Item 9	Business Continuity Phase five planning [HTA 12/20]	
	40. Louise Dineley presented this paper to the Board.	
	41. The Board was informed that the HTA was working in smarter ways in keeping with the changing landscape and that the emphasis was now on looking at the strategic and regulatory model and reviewing how this may look different once the HTA returns to a more normal way of working. The Board was also asked to note that the HTA would be strengthening partnerships with other regulators.	
	42. The Board was referred to the associated power point presentation and it was emphasised that the HTA would be prioritising core functions as part of phase five planning.	
	43. The Board noted the content of this paper.	
Item 10	Deemed Consent Implementation [Oral]	
	44. Allan Marriott-Smith presented an oral update to the Board.	
	45. The Board was informed that Codes A and F had been approved.	
	46. The Board was asked to note that NHSBT had been unable to complete Specialist Nurses Organ Donation (SNOD) training on deemed consent due to staff redeployment. This would need to be completed before the new legal provisions will be used in practice. The Board was informed that the HTA would be communicating an identical position on the law change as NHSBT.	
	47. The Board was updated on the work being carried out on the out of hours rota and that this would be presented at the next Board meeting.	
	48. The Board noted this update.	
	Action 2: An update to be provided to the Board on the progress made with changes to the operation of the HTA's out of hours rota	**JP**

Item 11	Any Other Business	
	49. Members noted that the next full Board meetings would take place using Zoom. An interim update will be organised to take place in June, also by Zoom.	8
	50. There was no other business raised.	

Date of next meeting- 16 July 2020

HTA July Board Meeting - Matters Arising from previous meetings

Meeting	Action	Update
May 2020	**Action 1:** Nicky Harrison to provide a fuller account of trends in SAEARs at the July Board meeting and thereafter **(ANH)**	To provide an update at the July meeting
Nov 2019	**Action 2:** The Executive to review the relevant policy to ensure it is clear on the criteria to be met for Panel consideration of a novel transplant case **(ANH)**	Agenda item 11 (July)
Nov 2019	**Action 3: Ongoing.** The Executive to consider using statistical process control techniques in reviewing incident data, such as for HTARIs **(ANH)**	To provide an update at the July Board meeting.
Nov 2019	**Action 5:** A proposal to be brought to a future Authority meeting on the possible remuneration for staff involved in the out of hours rota. **(ANH)**	Agenda item 11 (July)
July 2019	**Action 13:** The Executive to carry out further scoping to support an electronic way of working. **(NS)**	Board to be updated as part of Board IT requirement project work

Board paper

Date	16 July 2020	**Paper reference**	HTA (15/20)
Agenda item	6	**Author**	Allan Marriott-Smith
			Chief Executive

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Chief Executive's Report

Background

1. This paper provides an overview of performance at the end of quarter one.

2. It provides the Board with an overview of core regulatory business, the progress of development projects, a summary of the financial position at the end of the first quarter, and a summary of people, resource and other key operational issues arising since the Board last met in May.

3. Whilst pressures associated with the response to COVID-19 have slightly eased by the end of the quarter, work continues to ensure that we balance our regulatory responsibilities, our development goals and respond to a fast-changing environment in an agile way.

Decision-making to date

4. This report was approved by the CEO on 9 July 2020.

Action required

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

General overview and strategic risks

6. Over the quarter, the HTA has made excellent progress in moving to remote working arrangements for all staff.

7. The HTA deployed its Critical Incident Response Plan in mid-March to manage its response to the COVID-19 pandemic. The Plan has proved effective in responding to the situation and business continuity has been maintained.

8. Site visit inspections were suspended for quarter one and quarter two. This has resulted in the failure to fulfil our statutory duty to inspect establishments in the Human Application sector every two years. The Board and Department of Health and Social Care (DHSC) sponsors are aware of this issue and the risks it poses. Work has commenced on developing alternative procedures to mitigate these risks.

9. As reported in HTA (16/20) we have, over the quarter, responded to stakeholder demand and actively managed Corrective and Preventative Action plans (CAPAs), SAEARs and HTARIs. The pandemic has affected our regulated sectors in different ways, and there has been pressure to manage the demands in the post-mortem sector associated with the licensing of emergency mortuaries.

10. In its assessment of risk in June, the senior management team concluded that all six risks remained stable since its assessment in May. Specifically, risk one (failure to regulate appropriately) has stabilised due to work underway to develop a desk-based assessment model. The strategic risk register for June is at Annex A.

Quarter Four Accountability

11. In view of the current circumstances, we are meeting our accountability requirements to the Department of Health and Social Care (DHSC) differently in the short term. DHSC colleagues have agreed to scrutinise Board papers as part of their accountability review and follow up with supplementary questions where required.

12. The HTA's sponsor wrote to confirm there were no concerns with our performance in quarter four and praised the HTA staff for their response in these exceptional circumstances. We expect to follow a similar model until we return to more normal ways of working.

Quarter One development projects overview

13. Four key development projects have been prioritised in 2020/21.

Implementation of Deemed Consent

14. The Deemed Consent law change was implemented on 20 May 2020. There has been no increase to enquiries as a result of the law change at present and we have worked collaboratively with NHSBT to ensure our communication remains aligned.

HTA Website redevelopment project

15. The project, its deliverables and key milestones have been reviewed in quarter one to ensure we have a clear plan and set of deliverables that will support the development of the HTA website and ensure that we meet the required accessibility standards.

16. Oversight of the development process is provided by NHS X. Each stage of the process from discovery through the Alpha and Beta development stages is assessed by NHS X with approval given to move to the next stage.

17. The development of the website will be informed by a number of different sources. In quarter one we completed user testing sessions with members of the public. Further sessions with professional stakeholders are due to be completed by mid-July. This testing is critical in informing the development.

18. During the Alpha phase we will work with the developer to construct a prototype of the new site, based on intelligence coming from user research, our web analytics, and other internal data. Following further testing we will be seeking further assessment from NHS X (estimated early September) to move into the Beta phase.

19. The Beta phase will include further testing through the commission of an accessibility audit, to ensure the new site meets new accessibility requirements when launched.

20. A final assessment is required by NHS X to gain approval to move into a live site. This final stage is scheduled for November 2020.

EU Exit / Transition preparedness

21. The work we carried out in 2019/20 in preparation for the UK's departure from the EU has set us in good stead for the transition period. As previously, we continue to plan to the legal default. We have used 2019 Annual Activity data collected from Human Application sector establishments to update our planning assumptions and carried out

focused work in quarter one to understand the impact of the Northern Ireland Protocol. We are in the process of revising our project plans to account for possible implications of COVID-19 on resourcing and interdependencies with other projects.

22. During quarter one there was an increase in enquires from stakeholders relating to regulation of the Human Application sector following the UK's departure from the EU. These were mainly from stakeholders seeking clarity on licensing changes following the end of the transition period.

Office Re-location

23. The HTA's relocation plans remain on track. The construction work is continuing, and the Department expect to have the formal handover of the completed floor in early September 2020. This allows for furniture and IT equipment to be installed – with the provisional first date available for occupancy being 12 October 2020. Although some organisations are expected to begin relocation to 2 Redman Place at that time, the HTA plan is for our move to take place in January 2021.

24. Our internal project team is working through a number of logistical issues, with plans for packing and moving stored documents being created for different scenarios relating to building access at Buckingham Palace Road.

25. It is now clear that all five organisations relocating to 2 Redman Place will be looking to revisit their accommodation requirements in the near future. Given that these requirements will take some time to work through, all five organisations, have committed to honouring their initial space commitment through to March 2022, at which point we hope to collectively consider future needs and potentially renegotiate occupancy levels.

Horizon scanning

26. Through horizon scanning we continue to monitor trends and emerging areas of focus relating to our remit.

27. Two areas receiving increased attention in quarter one related to: consent provisions for imported material; and, licensing requirements for the removal of relevant material from the deceased.

Finance

Financial position for Q1 2020/21

Table one: Income summary

Human Tissue Authority
Income Summary
For the Three Months Ending 30 June 2020

| | Year to Date | | | |
| | Actuals | Budget | Variance | |
	£	£	£	%
Grant In Aid				
GIA	176,000	161,000	15,000	9.32%
Non Cash cover	51,405	51,405	0	0.00%
Sub-Total	**227,405**	**212,405**	**15,000**	**7.06%**
Licence Fees				
Application Fees	4,050	0	4,060	0.00%
Sub-Total	**4,050**	**0**	**4,050**	**0.00%**
Other				
Other income (Rent)	91,947	92,500	(553)	-0.60%
Other income (Secondees)	11,696	11,738	(41)	-0.35%
Devolved Assemblies	133,572	138,448	(4,876)	-3.52%
Sub-Total	**237,215**	**242,685**	**(5,470)**	**-2.25%**
Total Income	**468,670**	**455,090**	**13,580**	**2.98%**

28. Table one shows the breakdown of income to date. The variance to budget within our Grant in aid **(£15K)** is the result of drawing down a higher sum this quarter with the balance being spread over quarters two to four.

29. We are yet to receive official confirmation of our funding from the Department, but it has been assumed we will receive the same as last year which includes funding for paying the increased NHSPS employers' pension contributions and cover for our depreciation and amortisation costs.

30. Licence fee income shows no activity as we have deferred billing of Human Application establishments until September.

31. Within other income there is a small variance of £5k against income from devolved governments. This is because the budget assumed a small increase which was subsequently not billed as part of our COVID-19 response.

32. Table two provides a summary position at the end of quarter one of the 2020/21 financial year, a year to date net surplus against budget of **£19k.** A more detailed breakdown is given below.

Table two: Summary management accounts

HUMAN TISSUE AUTHORITY
Summary Management accounts for the period
For the Three Months Ending 30 June 2020

	Year-to-date				
	Actual	**Budget**	**Var**	**Var**	**Forecast**
	£	**£**	**£**	**%**	**£'000s**
INCOME					
Government Grant in Aid	176,000	161,000	15,000	9.32%	644,000
RF RDEL	51,414	51,414	0	0.00%	205,660
Licence Fee income	4,050	0	4,050	0.00%	3,941,530
Devolved Governments	133,572	138,448	(4,876)	(3.52%)	133,572
Rental income	91,947	92,500	(553)	(0.60%)	369,447
Other income	11,696	11,738	(41)	(0.35%)	46,909
TOTAL INCOME	**468,679**	**455,099**	**13,580**	**2.98%**	**5,341,118**
OPERATING COSTS					
Staff costs (salaries etc)	763,906	810,013	(46,107)	(5.69%)	3,118,034
Other staff (exc inspection)	6,624	14,830	(8,206)	(55.33%)	114,990
Authority costs	40,107	42,770	(2,663)	(6.23%)	171,637
Inspection costs	(318)	0	(318)	0.00%	41,682
LODT costs	307	0	307	0.00%	9,000
Communication costs	9,312	2,619	6,693	255.57%	32,817
IT and Telecom costs	98,269	80,615	17,654	21.90%	372,454
Office and Administration	4,665	4,695	(30)	(0.65%)	18,094
Other costs	17,791	15,960	1,831	11.47%	112,941
Legal and Professional costs	39,281	23,250	16,031	68.95%	109,031
Accommodation	207,869	203,375	4,494	2.21%	817,994
Non-cash costs	56,095	51,415	4,680	9.10%	224,376
Development Programme	0	0	0	0.00%	198,068
Total operating costs	**1,243,906**	**1,249,542**	**(5,635)**	**(0.45%)**	**5,341,118**
Net Income/(expenditure)	**(775,227)**	**(794,442)**	**19,215**	**(2.42%)**	**(0)**

Expenditure (by exception)

33. **Staff costs (salaries)** - year to date we are under budget by **£46k** (5.69%) and this is due to vacancies being carried, mainly at Manager level, since the start of the year.

34. **Other staff costs** – are underspent against budget **(£8k)** which is largely due to underspends within conference travel and training.

35. **Site visit costs** – there is no expenditure in the first quarter due to deferment of site visits until the latter part of the year.

36. **Communication costs** - are over budget by **£7k.** Costs relating to Code of Practice publication costs (£2k) and online survey costs (£5k).

37. **IT and Telecom costs** – are over budget due to the inclusion of costs relating to the annual cost of the new Office 365 licences which overlap the end of the current contract and additional support costs included in the initial budget

38. **Legal and professional costs** – are overspent by **£16k** that is the result of the consultancy work that began at the end of 2019/20 and was completed in May, the cost of which is apportioned to this year.

Forecast outturn

39. We have undertaken a first review of our plans for the remainder of the year and this has been reflected in our forecast.

40. Currently we are forecasting a balanced position. This takes into account all current plans and includes a reduction in our site visits budget. Work pertaining to the Development Programme will be funded from the current forecast surplus. The utilisation of these funds will be overseen by SMT and discussed and approved over the remainder of the year.

Other key performance indicators

Debtors

41. Our outstanding debtors as at 30 June 2020 is **£0.4m** compared to **£0.6m** in the same period last year. The outstanding amount is represented by **45** accounts of which:

- **19** (£45k) relate to the 2018/19 business year. We have pursued these accounts through chaser letters and telephone calls and will continue to do so particularly as we will be issuing invoices for the new fee year in September.
- **25** (£333k) relate to the 2019/20 business year and will be pursued in advance of the September billing run.
- **1** account is not due as the invoice was raised in June for the Welsh Government (£62k).

42. Below is a breakdown by sector of the outstanding debts as at 30 June 2020.

Table Three: Debtors by sector

SECTOR	Number of accounts	Value of debt	%ge
NHS	23	92,000.00	21%
Gov't bodies/ALBs	2	305,000.00	69%
Non Gov't bodies/NHS	20	44,000.00	10%
Total	**45**	**441,000.00**	100%

Financial risks

43. Financial risks are monitored on an ongoing basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – is currently rag status yellow, which remains unchanged from the previous quarter.

44. The impact of COVID-19 is noted in this assessment and a new, albeit medium to low proximity, risk relating to cashflow has been added to the key risks table.

Table Four: Risks and mitigations

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

People overview

COVID-19 response

45. HTA staff have not attended the office since 16 March. From a people perspective, quarter one has been characterised by supporting staff in the move to remote working, helping them to manage their work/life balance and wellbeing, and latterly, ensuring that regular human resources functions and processes are maintained.

46. New supplementary guidance on flexible working was developed and launched to support staff in balancing home and work commitments. The guidance encourages staff to consider how they might best deliver their objectives in challenging circumstances including managing home schooling, caring responsibilities and their own mental and physical health. A range of options are open including dividing the working day into active and non-active periods and working in the evening and or at weekends (subject to taking adequate rest periods).

47. A home risk assessment was undertaken at the start of the quarter by all staff and repeated six weeks later. This included the need for IT equipment, ergonomic office set up and home security, including personal safety. The Head of HR contacted every

member of staff individually regarding their submission and the required equipment or furniture was approved for purchase.

48. Daily 'virtual coffee breaks' were introduced in the early stages of the pandemic. These were hosted by a member of the SMT or Head of HR. Staff were encouraged to talk about non work-related issues and to air concerns. The need for this initiative has reduced significantly and is now combined with twice weekly SMT drop in sessions.

49. Daily, and latterly weekly, HTAMG situation report (sitrep) meetings were initiated to ensure transparent and timely communication between SMT and Heads of function as the pandemic situation and the HTA's response evolved. These meetings continue but discussing day to day business, as the situation has stabilised.

Wellness

50. The Wellbeing Programme has been further developed through the period of the pandemic taking full advantage of Wave (the HTA's intranet).

51. Wellbeing material posted has included Stress Awareness in Lockdown, Toolkits for Line Managers with Remote Teams, Working from Home and Healthy Working along with a Top Tips guide.

52. We have also built a monthly topic programme that has been further supported by weekly connected themes. These have included Managing Mental and Physical Fitness, Staying Connected, Care for Carers and Heathy Eating.

53. We developed and launched Diversity and Inclusion page on Wave raising awareness of national and international events and celebrations.

Pulse survey

54. We conducted a Pulse survey in early May to judge how well staff believed the HTA had responded to COVID-19 and lockdown. The survey had an 85% response rate and the results ranged between 79%- 83% positive for each of the 5 questions.

Training

55. The following training-related activities have been undertaken over the quarter:

- a training page with links to many free online training programmes was launched on Wave;
- three Line Managers attended a three-month modular online Leadership course;
- HTA Act training was delivered by Field Fisher segmented into four separate online sessions that have been recorded for future viewing;

- the Career Investment scheme was opened for staff to apply and four members of staff have requested support though this scheme; and
- the Lunch and Learn programme covered topics including trans equality and unconscious bias, introduction to projects and creating and using dashboards in CRM.

Personal Development Plans (PDPs)

56. All staff have held and recorded end of year PDP reviews with their line managers. A new simplified PDP form has been launched for 2020/2021, with a new automated toolkit planned for 2021/2022.

57. A Competency Framework has been developed to guide the behaviours that form part of measures within the PDP objectives and is in pilot stage.

Recruitment and Retention

58. Recruitment has been on hold during the pandemic. We have developed and are currently piloting a new induction programme. This has been used to successfully induct three new members of staff over the quarter, whose job offers were in place before the lockdown. Feedback to date has been very positive from the new starters and their line managers

59. We currently have five vacancies, three Regulation Managers, one Administrator and the Governance and Quality Manager.

Other

60. The positive and inclusive culture of the HTA has been externally recognised with an accreditation by Business in the Community Race at Work Charter and Disability Confident Charter. We have received the 'badge' from the Race at Work Charter which has been added to the Internet, Wave and all internal external documentation. We expect the Disability Confident badge in the coming days.

Freedom of Information requests

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

Complaints

62. In quarter one, no complaints were received by the HTA.

HTA Strategic Risk Register
June 2020

The escalating impact of the coronavirus pandemic has enforced changes in ways of working and our ability to oversee the sectors we regulate using existing processes and practices. Authority Members have been updated on issues as they emerge - the SRR currently presents the assessment of the remaining areas of strategic risk.

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are: *failure to regulate appropriately* - the score for which has increased as a result of the removal of routine site visit inspection as a regulatory tool and the current position on introducing an alternative; *failure to manage expectations of regulation*, which reflects the fast-pace of change within the sectors we regulate, the low likelihood of legislative change in the foreseeable future and the removal of routine site visit inspection as a regulatory tool; *failure to utilise our capabilities effectively*, which reflects the fact that business plans are being redeveloped at pace to adjust to the current limitations on activities as a result of government restrictions. The organisation has adapted to this new working environment and is developing new regulatory tools that will allow continued oversight of our sectors. At this time SMT believe the overall risk level has levelled out

Other notable risks: Post EU departure, understanding the impact and resource required to deal with the impact of the departure is proving challenging. Horizon scanning for emerging issues and liaison with DHSC remain a key focus.
Progress on other development activity regathered pace during January and February with additional funds available to year end being invested for optimum benefit in the next business year. In particular, work to support our office move, or which builds a foundation for future development. Work is commencing to scope the development priorities for the coming twelve months.

DHSC spending controls will place continuing pressures on ALBs to make savings. We have received verbal confirmation of GIA funding for the 2020/21 financial year, but we will continue to be unable to access reserves to fund our wider development project ambitions - we have considered some options to provide funding in this new financial year to enable the completion of the development work we undertook last financial year and to contiue progress.

Risk	Mar 2020	Apr 2020	May 2020	June 2020	Comments
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)	↑	↑	→	→	A good regulatory framework and processes are in place, with a strong assured position on our key regulatory processes confirmed in the recent internal audit of these processes. Further continuous improvement is planned through mechanisms such as the recently introduced quality forum and the investment in the new one-year role of Regulation Manager - Training. Regular training sessions coupled with work to improve and standardise reporting processes along with an increasing focus on using data and data quality is also improving this area. The introduction of the new Inspection Report templates reduces the risk of inconsistencies in reporting which we feel has a positive impact on this risk. The restrictions imposed by government to manage the pandemic mean that the statutory obligation to inspect in the HA sector cannot be met; this being managed as an issue (and the Board and DHSC sponsors are aware of this). The removal of routine site visit inspection as a regulatory tool (in the absence of an alternative) results in increased risks in some sectors, but is moderate to low in others. Action to assess the viability of desk-based model is underway and may provide greater assurance while site visit inspections remain suspended. This position has stabilised over the past month as our work to developed a desk-based assessment model is underway and the increased pressures in the post-mortem sector have now levelled off.
2 - Failure to manage an incident (Delivery, Development and Deployment)	↑	→	→	→	Plans are in place to manage an incident. We have received the final reports from the internal audit review of our Business Continuity and Critical Incident Management arrangements providing moderate levels of assurance in both areas. Actions will be discussed with ARAC in due course. The response to managing the impact of the pandemic using the existing plans has been a significant stress test of their adequacy. They have not at this point proved wanting. At present the greatest concern is the emergence of another significant incident in parallel that results in compound management stretch. SMT believe this risk has not increased in June 2020.
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)	→	↑	→	→	We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but which may adversely impact on public confidence is challenging. Looking forward, the Development programme has included a specific workstream to strengthen horizon scanning on emerging changes to policy or activities where the HTA may be required to act or offer an authoritative voice. This proactive approach should support the constant number of perimeter issues as well as activities over the transition period. The maintenance of the risk level in this area reflects the dynamic period of the quarter which has included the establishment of contingency arrangements in response to the coronavirus emergency, the "go live" of deemed consent and the delivery of some early thinking of developments required as part of the transition. Each of these themes has required developments and changes to ways of working and further updating of communications on our role, guidance to licensed establishments and the maintenance of public and stakeholder confidence. The results of stakeholder evaluation commissioned in quarter 4 19/20 will be reported to the July Board meeting. The report is broadly positive and provides insight to opportunities that can be strengthened and hence included in developments in 2020/21. SMT believe this risk has not increased in June 2020.
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	↑	↑	→	→	We are now using the skills of our more recent recruits more fully. Recruitment is currently on hold, until business plans can be developed over a longer time horizon. There are not, however, any capability gaps that are impeding the achievement of current objectives. Workload and pressure on staff continue to be monitored closely by the management team, and improvements in management information have been introduced in May to support this. ARAC has supported the temporary deprioritisation of the response to the records management internal audit. As a result, the HTA will be tolerating a degree of risk in the medium term. The scoping of development of our EDRMS forms part of development plans for 2020/21 building on the preparatory work completed in quarter 4. This work is currently planned for late quarter 2 and early quarter 3. The sequencing of this work will need to take into account interdependencies across the development programme. This risk experienced upward pressure initially as a result of the current status of our response to the pandemic: anticipating reduced staff capacity and also reduced utilisation as some BAU activity cannot be undertaken and there will be a lag until decisions are taken on how best to utilise excess capacity. The contingency planning for managing capacity and capability needs has been deployed although the full extent of our planning was not required. As a result the residual risk rating is stable and has tthe potential to decrease at the end of quarter 1 if the current trajectory is maintained, the reframed Q1 business plan is delivered and we continue to prioritise resource deployment to the identified core business priorities. Our June assessment was no change in this risk scoring
5 - Insufficient, or ineffective management of, financial resources (Deployment b)	↑	↑	→	→	We await final confirmation of the GIA settlement for the 2020/21 financial year from DHSC finance colleagues, although we have received indications that the 19/20 GIA settlement will roll forward this is unlikely to be confirmed until late May/early June when DHSC finalises its overall budgetary position. The ability to maintain the organisation and ensure continuity of payments and salaries processing could be impacted by the pandemic. Although the decision to defer invoicing for the HA sector until September does not represent an explicit risk, the wider implications for organisations in all sectors unable to undertake activity could reduce income for 2020/21. At present we believe this to be a increased likelihood which has increased the pressure on risk 4 and this heightened position will likely continue for the first half of the financial year.
6 - Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)	→	↓	→	→	DHSC did not agreed funding for this Programme in the 19/20 business year which delayed planning and project initiation. Some funding became available in quarter four which allowed significant progress to be made, and the foundations laid for future development. The office move project is underway and progressing well, our interim PM is now in the process of handing the project to the HTA's new PM. The impact of the move on other activities in the next business year are being accounted for and this remains one of our priority activities for the next year. This new PM will also support detailed planning of the next phase of our transformation work. Although there has been more uncertainty about the timing of the office move the successful delivery of a number of projects to the end of the 2019/20 business year (HTA Intranet, Office 365 upgrade, adoption of remote working, future EDRMS requirements and data and intelligence review) has lead to a downgrading of the impact and likelihood score for this risk - now 3/3. There is still more to do, but the work to date represents a significant proportion of the "must do" element of this programme.

Strategic Objectives

Delivery objectives
• 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.
• Deliver effective regulation of living donation.
• Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit.
• 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.
• 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 objectives
• 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.
• Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
• 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.
• Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

Deployment objectives
• Manage and develop our people in line with the HTA's People Strategy
• 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

Risks are assessed by using the grid below

Risk scoring matrix

Impact		1. Rare (<10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
	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

Risk Score = Impact x Likelihood

Likelihood

Lines of defence are:
1 - Embedded in the business operation
2 - Corporate oversight functions
3 - Independent of the HTA

Lines of defence	
1.	Management control and internal controls (frontline)
2.	Risk Management functions (senior management)
3.	Internal Audit (board/audit committee)

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LoD 1	LoD 2	LoD 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	4	Ongoing	**Regulatory model**	5	2							
						HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model			In the current absence of site visit inspection, work will be undertaken to develop a risk assessment and desk-based assessment proposal. A revised strategy reflecting this change is in development.	X			Preventative	Authority developed and approved the current HTA Strategy and is aware of the risk associated with current impossibility of site visit inspections.	HTA Strategy published in May 2019 and report on the proposals for desk-based inspection was made in May 2020.
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory Delivery Report made in February 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.
						Annual scheduled review of Strategy				X	X		Preventative	Outputs from annual strategy review translate into revised annual Strategy	Annual strategic planning away day completed in January 2020.
						HTA is currently producing quarterly business plans as a result of the coronavirus pandemic. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.				X	X		Preventative	Business plan for 2019/20 signed-off by the Interim Chair on behalf of the Authority and by sponsor Department at the start of the year.	Quarterly reporting to Authority and DHSC in May 2020 reflected progress against quarterly business plans.
						Well established processes support our core regulatory business.						X	Detective	Internal audit conducted on Key Regulatory Processes, receiving substantial assurance and noting good areas of best practice	Final report received April 2019 and showed substantial assurance. Two low priority recommendations have been followed-up with actions 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				X			Preventative/ Monitoring	Identified staff member temporarily responsible for QMS, automated review reminders, management oversight of progress on updates	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 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 Authority				X			Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made at May 2020 Authority meeting. Year-end PDP reviews due to be completed by end June.
						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, Regulation-led (RM-Training Programme) e.g. quarterly Regulation Training Mornings (most recent being 1/6/20) and '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.	X	X		Preventative/ Monitoring	SMT assessment of skills requirements and gaps as vacancies occur, Recruitment policy	Staffing levels and risks reported quarterly to the Authority Recent vacancies have been used to introduce new skills to the HTA e.g. recruitment of a data analyst in January 2020, recruitment of a project manager and inward secondments to support intranet development activity and management of FOIs.
						Transition period									
						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.			Fortnightly Transition Period oversight meetings from February 2020 with a standing item on the SMT agenda. Continued close liaison with DHSC policy and communications teams, through fortnightly catch-ups of DHSC with ALBs. High level resource planning done for 2020/21 business plan in preparation for anticipated changes at the end of Transition Period.	X	X		Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Short fortnightly Heads meetings give an overview of any enquiries and feedback steers and guidance from DHSC. These are reported to SMT.	Minutes of weekly SMT meetings.
						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		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL			ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L								
2	**Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:** • **relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)** • **caused by deficiency in the HTA's regulation or operation** • **where we need to regulate, such as with emergency mortuaries** • **that causes business continuity issues** **(Risk to all Delivery Development and Deployment objectives)** Risk owner: **Nicky Harrison**	_**Cause**_ • _Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)_ • _Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)_ • _Failure to work effectively with partners/other organisations_ • _Breach of data security_ • _IT failure or attack incident affecting access to HTA office_ • _External factors such as terrorist incident, large scale infrastructure failure or pandemic_ _**Effect**_ • _Loss of public confidence_ • _Reputational damage_ • _Legal action against the HTA_ • _Intervention by sponsor_	5	3	Future, should event occur	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	3	2			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.
						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.	CIRP reviewed and updated to version 19 in July 2019. Further minor changes proposed February 2020 updated roles following staff changes.
						Media handling policy and guidance in place and Critical Incident Response Plan includes requirement to involve Comms team. Comms Team have embedded media handling and development of lines to take into business as usual.				Comms Team maintain close working relationships with colleagues across the business and proactively raise awareness of the need for Comms role in shaping lines and dealing with media.	X			Preventative	Policy reviewed as scheduled. Reports on media issues and activity in Delivery Report. Evidence of active Comms Team participation in issues with potential for media or public interest.	Media issues are included in the Delivery Report as they arise and as relevant.
						Availability of legal advice					X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy					X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT - three referred to in February 2020 Delivery Report for Q3 of 2019/20.
						Onward delegation scheme and decision making framework agreed by the Authority					X	X		Preventative	Standing Orders and Authority minutes	Standing Orders published May 2017, due to be updated in 2020.
						Regulatory decision making framework				Regulatory Decision Making process and SOP regularly reviewed and disseminated to staff.	X			Preventative	Reports to Authority of key decisions in Delivery Report	RDMs summarised in Delivery Report to Authority Meeting in February 2020 for Q3 or 2019/20. Regulatory Decision Making SOP reviewed and updated February 2020.
						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.
						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 in March 2020.
						Evaluate test exercise of incident and feedback to all staff.				Question over whether a test of the Plan is required in light of the recent stress test presented by the coronavirus pandemic.	X			Preventative		
						Ensure DIs (or equivalent in ODT sector) are aware of and follow the incident reporting procedure for incidents reportable to the HTA.					X			Preventative / Detective / Monitoring	Inspections (and audits for ODT) include assessment of licensed establishments' knowledge and use of the relevant HTA incident reporting process.	Findings at inspection. Monitoring establishments' reporting of incidents through the HTARI, HA SAEARs and ODT SAEARs groups.
						Management of Transition Period to 31 December 2020 following the UK's departure from the EU								Preventative / Detective / Monitoring	Engagement with DHSC on planning for the end of the transition period. Director-level oversight as SRO (Director of Regulation), fortnightly oversight meetings with relevant Heads, regular reporting to SMT.	Regular reports to SMT - standing item on SMT agenda from February 2020.

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK L	ACTIONS TO IMPROVE MITIGATION	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*	Log of issues known to the HTA with respect to the legislation to inform DH and manage messages	4	3			X		Monitoring	Ongoing log	Log in place and reviewed at HTAMG quarterly. New issues identified in causes and effects Reviewed by HTAMG in September 2019
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope					X			Preventative/ Detective	Stakeholder Group meeting minutes Authority minutes (including Public Authority Meeting) TAG and HWG meetings	Last stakeholder group meeting in October 2019 Public Authority Meeting in May 2019; Histopathology Working Group *February 2020*; Transplant Advisory Group *October 2019*
						Active management of issues raised by the media – including the development of the HTA position on issues					X			Preventative/ Detective	Quarterly reports to Authority on communication (including media) activities	Last report to Public Authority Meeting *February 2020*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence					X		Monitoring	Quarterly Accountability meetings with DH	*Quarterly* accountability meeting in *January 2020*
						Action where we believe it will support public confidence					X			Preventative	*Updated guidance in response to the coronavirus emergency published on the website, further sector specific guidance also published. These publications reflect the importance of ongoing publications and updates to specific conditions.*	Update to the Board and DHSC at Board meeting May 2020.
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge					X			Preventative	Duty and its uses understood by SMT and Chair	Letter to Minister re. import and consent requirements for public display *Autumn 2018* *Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, 2020.*
						Legal advice now gives a clearer view of our Schedule 2, s. 20 powers					X			Preventative	Legal advice to be followed	Legal advice September 2016. No change to position.
						No further changes to HTA's Standards since significant changes launched April 2017 but significant activity to update Codes of Practice for Organ Donation and Transplantation (and consent) to support the introduction of deemed consent for organ donation, with the new law due to go live in May 2020.					X			Preventative	*Updated guidance published. Updated Codes of Practice to support deemed consent published.*	*Supplementary guidance on PM standard on traceability issued Feb 2019.* *Further guidance developed on PM Standards in consultation with HWG, eg on three points of identification, long-term storage of bodies and dealing with consent for testing for infection of deceased in cases of sharps injuries.* *Updated Code of Practice for Organ Donation and Transplantation laid in Parliament February 2020.*
						Partial implementation of triennial review recommendations **March 2017**					X			Preventative and remedial	Recommendations form part of business plan	*Good progress, most complete with only benchmarking not completed and no longer planned as a priority.*
						Extensive Professional Evaluation Survey being undertaken in Q4 2019/20. Report to Board in July 2020.					X			Preventative		*Evidence of Professional Evaluation Survey being commissioned and started in Q4 2019/20. Due to report to SMT in June and the Board in July.*
						Proactive horizon scanning and development of policy in emerging/complex areas. Further strengthening building on existing system.					X			Preventative	HTAMG Minutes	Horizon scanning map in use and reviewed quarterly by HTAMG Horizon scanning standard agenda item at all stakeholder group, TAG, HWG
									Deliver programme of work to improve relationships with licensed establishments	X			Preventative	Programme monitored by SMT and HTAMG	Programme underway Licensed establishment engagement programme established to inform work New ToR for internal group to agree focus for next business year

| | | | | | | | Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners) to inform planning for the Transition Period and the period after 31 December 2020. | | x | | | Preventative | Development programme workstream 20/21. Programme reporting via a fortnightly steering group and weekly updates to SMT. | |

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
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 Heads* • *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*	4	4		**People**	4	4							
						Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle				X	X		Preventative/ Monitoring	QMS reminders as policies due for review. SMT review of all revised policies	Regular review cycle recommenced in late summer
						Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review) Standard objectives for all line managers				X	X		Preventative/ Monitoring	PDP guidance reviewed annually and approved by SMT, newly introduced countersigning officer check	Guidance issued April 2019. End of year guidance has been issued and process commenced.
						Regular review of HTA organisational structure and job descriptions				X	X		Preventative	Recruiting to the currently agreed organisational structure and approved job descriptions	Role and job descriptions reviewed as posts become vacant. Decision to recruit driven by business needs rather than assumes like for like replacement.
						Feedback from HTA people about work, management and leadership				X	X		Monitoring/ Detective	Staff survey, exit interviews, staff forum (attended by SMT Member and Head of HR)	Staff Survey completed Janauary 2020, action plan to be developed in Q4. ARAC chair regularly discusses staff issues with chair of staff forum.
						Revised People Strategy 2019 to 2021 in January 2020				X			Preventative/ Monitoring	Authority approval of the Strategy	Authority approved the Strategy at its meeting in February 2019. Update provided to Board Strategy session in February 2020.
						Data									
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)				X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019
						Appropriate procedures to manage personal data inlcuding 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									
						Staff training in key business systems				X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New induction programme to be launched Summer 2020.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date				X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2019
						Business technology									
						Identify refresher training and targeted software specific training needs.				X			Preventative	Evidence of targeted training in last quarter. Further strengthening of core training requirements included in updated induction programme.	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
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	4		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Last review January 2019 - revised versions to go to SMT in July 2020
						Financial projections, cash flow forecasting and monitoring				X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report to Authority November 2019
						Licence fee modelling							Preventative	Annual update to fees model	Update agreed by the Authority November 2019 meeting
						Rigorous debt recovery procedure				X			Preventative	Monthly finance reports to SMT and quarterly to Authority	This has changed in response to COVID19 impact on licence holders - April licence fees have been deferred until September. Although we maintain a tight grip on our position the oberall 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 2019
						Delegation letters set out responsibilities				X	X		Preventative	Delegation letters issued annually	Issued in May 2020
						Prioritisation when work requirements change				X			Preventative	Agreed business plan, monthly HTAMG and SMT reports	Last HTAMG report October 2019 Last SMT update January 2020
						Fees model provides cost/income information for planning				X			Preventative	Annual review of fees model, reported to SMT and Authority	Update agreed by the Authority November 2019.
						Annual external audit						X	Detective	NAO report annually	Last report in June 2019 - clean opinion
									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 January 2020
									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 2019/20 - last met July 2019 DHSC Finance wrote in September indicating confirmation of GIA funding sometime in October 2019 Confirmation of 2020/21 GIA recovered in December 2019 - no formal Inote of delegation st present.
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	X	X		Preventative	Counter fraud Strategy and Action Plan devleoped and presented to ARAC Oct-19. Annual training of staff completed n Q4	*Cabinet Office responses/feedback, although fraud prevention now part of BAU for the organisation.*

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LOD 1	LOD 2	LOD 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
6	Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d) Risk owner Louise Dineley	**Causes** • Uncertainty of funding • Programme and project benefits poorly defined and understood • Inadequate programme and project governance arrangements • Poorly specified programme and projects • Insufficient programme, project and change management skills • Inadequate leadership of change • Inability to access the necessary skills required at a affordable cost • Lack of staff buy-in to change • Management and Head stretch of delivering transformation alongside business as usual and other development activity • Insufficient agility in (re)deploying people to change projects • Poorly specified procurement and inadequate contract management • Realisation of single points of failure for DDAT and People Strategy **Effects** • Wasted public money • Failure to achieve the central strategic intent of the Authority • Distracts senior management from operations at a time when demands have increased • Reputational damage • Unaffordable cost over run • Staff demotivation • Data remains under-utilised • Technology inadequate to meet future needs (cost, functionality) • Limited ability to achieve improvements in efficiency and effectiveness • Pace of change is inadequate and impacts negatively on other work	5	4		SMT experience of organisational change, programme and project management	3	3		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 PRINCE2)				X			Preventative		
						A number of trained project managers among HTA staff				X			Preventative		
						Experience of procurement and contract management				X			Preventative		
						Existing mechanisms for engaging staff				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				X			Preventative		
						Obtain external advice on programme design and implementation				X			Preventative	Advice provided by PPL to SMT in April 2019	
									Implementation of external advice on programme design and governance	X			Preventative	PPL presentation to SMT April 2019	
									Embed Benefits Realisation Management methodology within programme	X			Preventative		
									Introduce a Programme Management Office	X			Preventative		New PM appointed, procedures and PMO to be established by…..
									Authority approval to proceed at key Gateway decision points		X		Monitoring		
									Act on the formal training needs analysis undertaken for the HTA more widely to identify and improve the level of internal capability to deliver the programme	X			Preventative	Formal training needs analysis data provided to HTA April 2019	
									Training plan to encompass project and change management and HTA approach	X			Preventative		
									Development of procurement plan to deliver the DDAT Strategy	X			Preventative		Plan in place, significant progress made at end of 2019/20 budsiness year and work ongoing on 2020/21 plan.
									SROs identified for Programme and individual projects	X			Preventative		
									Schedule a regular programme of staff engagement events	X			Preventative		
									Establish an external stakeholder communications and engagement plan	X			Preventative		
									Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		
									Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
									Appointment of external critical friend to counter potential optimism bias			X	Preventative		

Authority paper

Date	16 July 2020	**Paper reference**	HTA (16/20)
Agenda item	7	**Author**	Nicolette Harrison
			Director of Regulation
Protective Marking	OFFICIAL		

Business Continuity- Regulatory Update

Background

1. This agenda item presents an overview of the HTA's regulatory operating environment during quarter one of 2020/21.

2. The annexes to the paper provide details of the volume of regulatory activity over the quarter and an assessment of the current position in each of the HTA's sectors.

Decision-making to date

3. This report was approved by SMT on 9 July 2020.

Action required

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

Board Supplementary Data Annex document
Quarter 1 2020/2021

Date	7 May 2020	Paper Reference	HTA (16a/20)
Agenda Item	7	Author	Louise Dineley
Protective Marking	OFFICIAL	Author Contact Louise.dineley@hta.gov.uk	

Purpose of Report

1. This report sets out a high level overview of activity in quarter one 2020/21.

Enquiries

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

Figure 1: Number of body donation and other general enquiries received each quarter
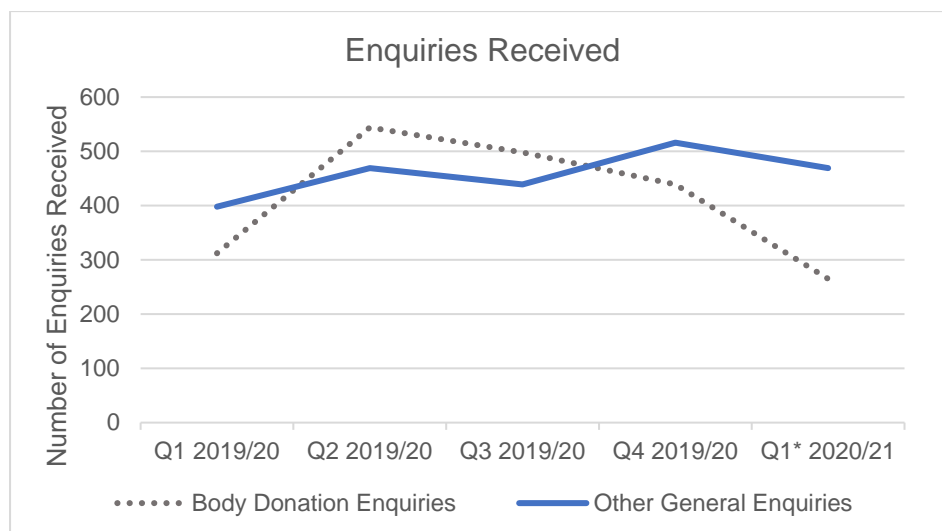
3. Table 1 displays the number of general enquiries received for each sector (excluding body donation enquiries).

Table 1: General Enquiries Received by sector (excluding Body Donation Enquiries)

Sector	Q1 2019/20	Q2 2019/20	Q3 2019/20	Q4 2019/20	Q1* 2020/21	2018/19 Total	2019/20 Total
Anatomy	30	42	43	21	19	160	136

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Human Application	73	62	78	103	96	282	316
Organ Donation and Transplantation	13	11	8	6	12	30	38
Post Mortem	59	85	88	147	190	178	379
Public Display	4	5	5	8	1	21	22
Research	52	68	75	53	71	139	248
Removal	1	2	1	0	5	1	4
No Sector Assigned	166	194	141	178	75	908	679
Total	398	469	439	516	469	1,719	1,822

Licensing

4. Table 2 displays the number of new licence applications, new licences offered, satellite additions and revocations in quarter one.

Table 2: New licence applications, new licences offered, satellite additions and revocations in quarter one

Sector	New Licence Application	New Licences Offered	Satellite Additions	Revocations	Satellite Revocations
Anatomy	0	0	0	0	0
Human Application	1	0	4	1	0
Organ Donation and Transplantation	0	0	0	0	0
Post Mortem	10	7	2	0	1
Public Display	0	0	0	2	0
Research	1	3	0	0	0
Total	12	10	6	3	1

5. Twelve new licence applications were received in quarter one 2020/21 (Ten were emergency mortuary licence applications in the Post Mortem sector, one application was received in the Human Application sector and one was received in the Research sector).

*Data period: 1st Apr – 28th Jun. May be subject to revision.

6. Ten emergency mortuary licence applications were received in quarter one and seven licences were offered.

7. Three new licences were offered in the Research sector in quarter one 2020/21

8. There were four satellite additions in the Human Application sector and two satellite additions in the Post Mortem sector

9. A total of three revocations took place in quarter one, one was in the Human Application sector and two in the Public Display sector. One satellite revocation took place in the Post Mortem sector.

Licensing Variations

10. Figure 2 displays the total number of licensing variations received each quarter

11. Licensing variations received by sector is displayed in Table 3.

Figure 2: Number of licencing variations received each quarter
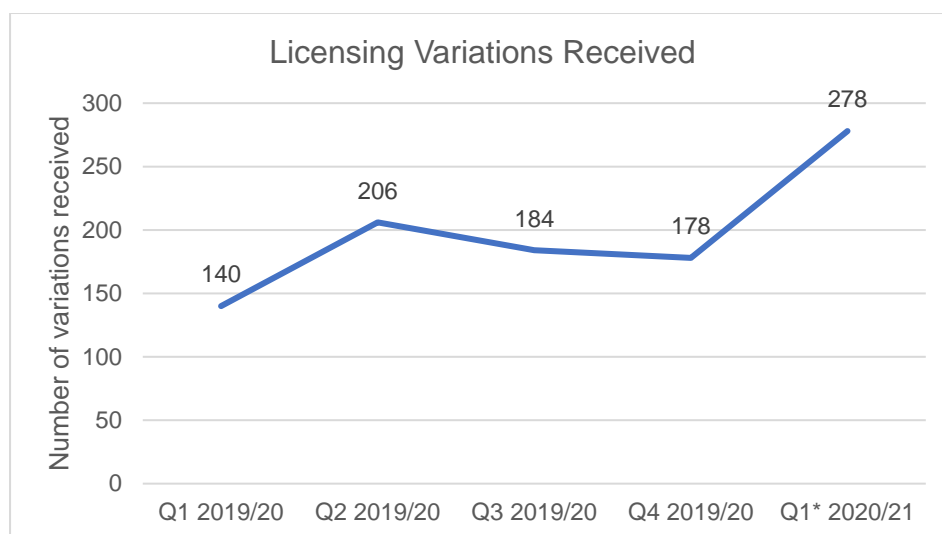
Table 3: Licensing variations received by sector

Sector	Q1 2019/20	Q2 2019/20	Q3 2019/20	Q4 2019/20	Q1* 2020/21	2018/19 Total	2019/20 Total
Anatomy	4	8	10	8	6	25	30
Human Application	54	72	54	83	124	260	118
Organ Donation and Transplantation	4	7	12	4	5	27	27

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Post Mortem	38	72	55	40	89	158	205
Public Display	1	5	9	1	5	9	16
Research	39	42	42	42	49	155	165
Removal	0	0	2	0	0	0	2
Total	140	206	184	178	278	634	708

12. New change categories introduced during the COVID-19 period has contributed to the higher number of licensing variations received in quarter one when compared to previous quarters. This includes the Minor Change variation which is a newly added category used to collect information that organisations have been asked to send us regarding their current activities. 61 of the 278 variations received in quarter one were Minor Change variations. The majority of these Minor Change variations involve suspension of activities due to COVID-19.

Living Donation

13. Figure 3 shows the total number of living donation cases approved by the LDAT and Board panels.

14. In quarter one 2020/21, 30 cases were approved by the LDAT and one case was approved by a Board panel. The total number of cases approved also includes those using the emergency out-of-hours processes.

Figure 3: Number of living donation cases approved per quarter
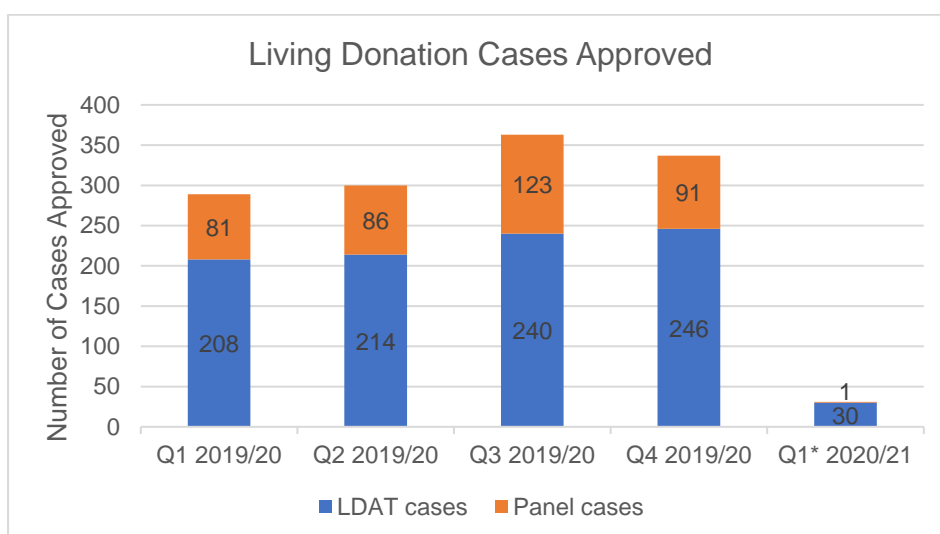
*Data period: 1st Apr – 28th Jun. May be subject to revision.

15. Table 4 below shows the total number of bone marrow and PBSC cases approved (donors are children lacking competence to consent) in quarter one compared to preceding quarters.

Table 4: Total number of bone marrow and PBSC cases approved

	Q1 2019/20	Q2 2019/20	Q3 2019/20	Q4 2019/20	Q1* 2020/21	2018/19 Total	2019/20 Total
Approvals	15	19	15	17	16	71	66

Incidents – HTARIs

16. Figure 4 displays the number of reported HTARIs in quarter one compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents.

Figure 4: HTARIs cases opened during quarter in the Post Mortem sector

HTARIs Opened

Cases Opened

44
59
60
54
30

Q1 2019/20   Q2 2019/20   Q3 2019/20   Q4 2019/20   Q1* 2020/21
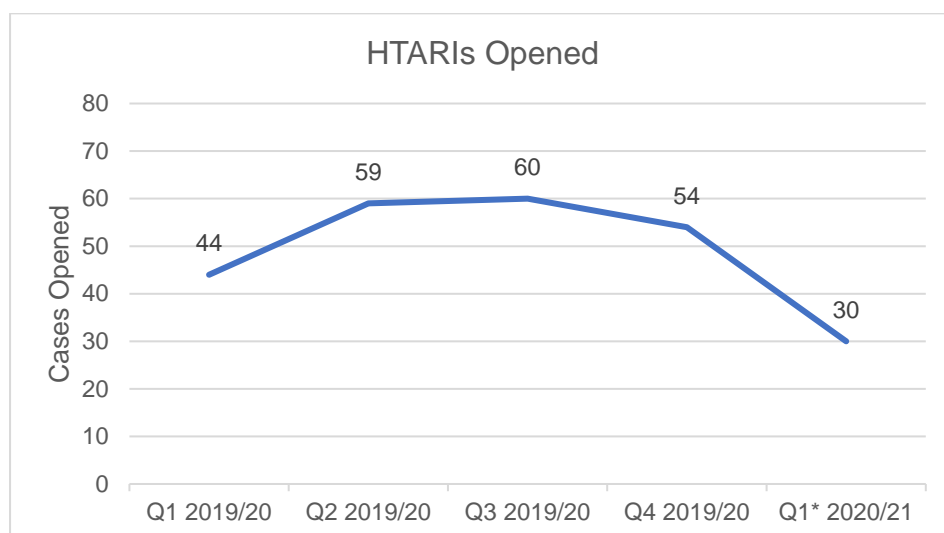
17. Figure 5 displays the number of HTARIs closed in quarter one compared to the preceding quarters.

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Figure 5: HTARI cases closed during quarter in the Post Mortem sector


HTARIs Closed
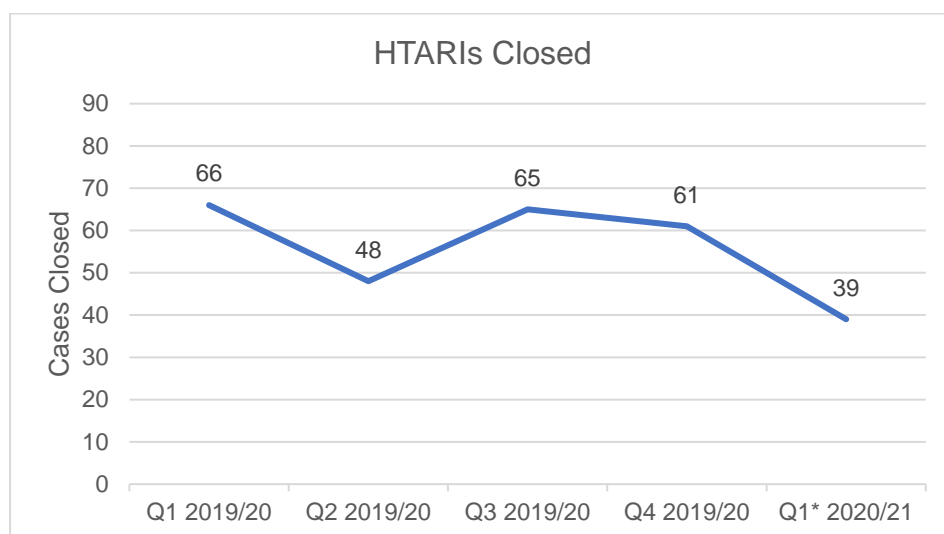
Incidents – HA SAEARs

18. Figure 6 below displays the number of reported HA SAEARs in quarter one compared to preceding quarters. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR.

Figure 6: SAEARs opened during quarter in the Human Application sector

HA SAEARS Opened
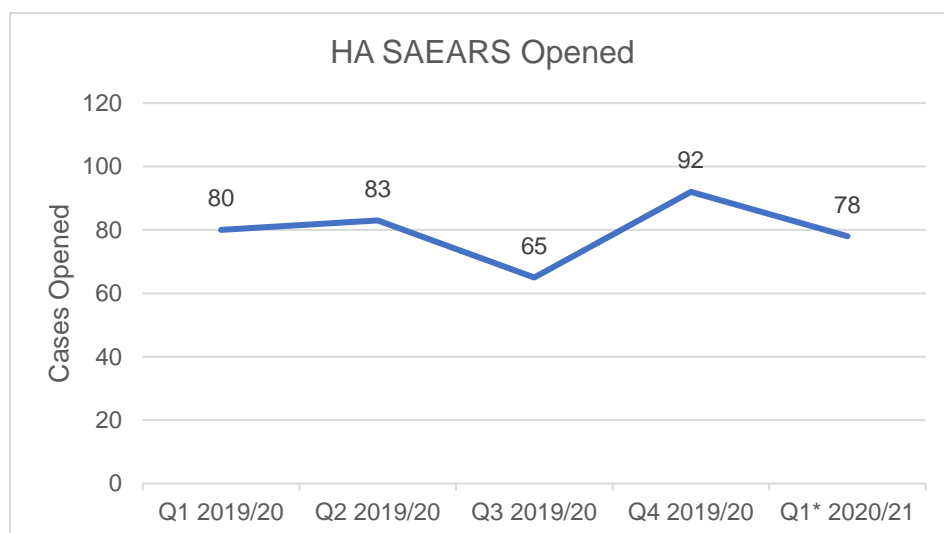
*Data period: 1st Apr – 28th Jun. May be subject to revision.

19. Figure 7 displays the number of HA SAEARs closed in quarter one compared to preceding quarters.

Figure 7: SAEARs closed during quarter in the Human Application sector

HA SAEARs Closed

74, 54, 178, 163, 105

Q1 2019/20, Q2 2019/20, Q3 2019/20, Q4 2019/20, Q1* 2020/21
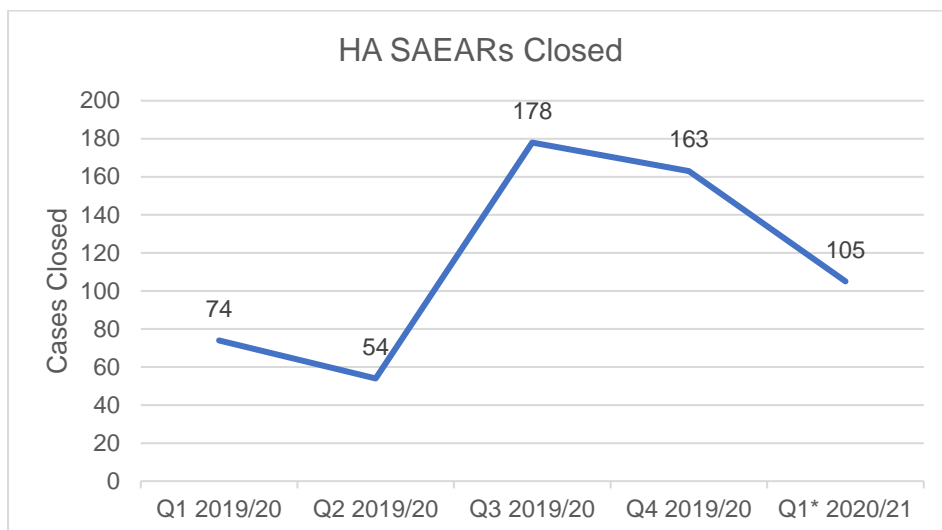
Incidents – ODT SAEARs

20. Figure 8 below displays the number of reported ODT SAEARs in quarter one compared to preceding quarters.

Figure 8: SAEARs opened during quarter in the Organ Donation and Transplantation sector

ODT SAEARs Opened

31, 19, 32, 23, 5

Q1 2019/20, Q2 2019/20, Q3 2019/20, Q4 2019/20, Q1* 2020/21
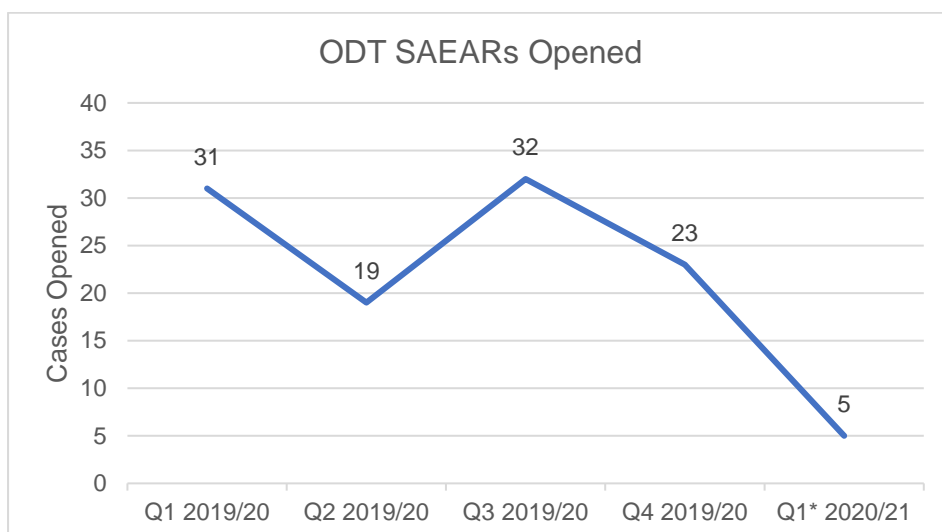
*Data period: 1st Apr – 28th Jun. May be subject to revision.

21. Figure 9 below displays the number of ODT SAEARs closed in quarter one compared to preceding quarters.

Figure 9: SAEARs closed during quarter in the Organ Donation and Transplantation sector
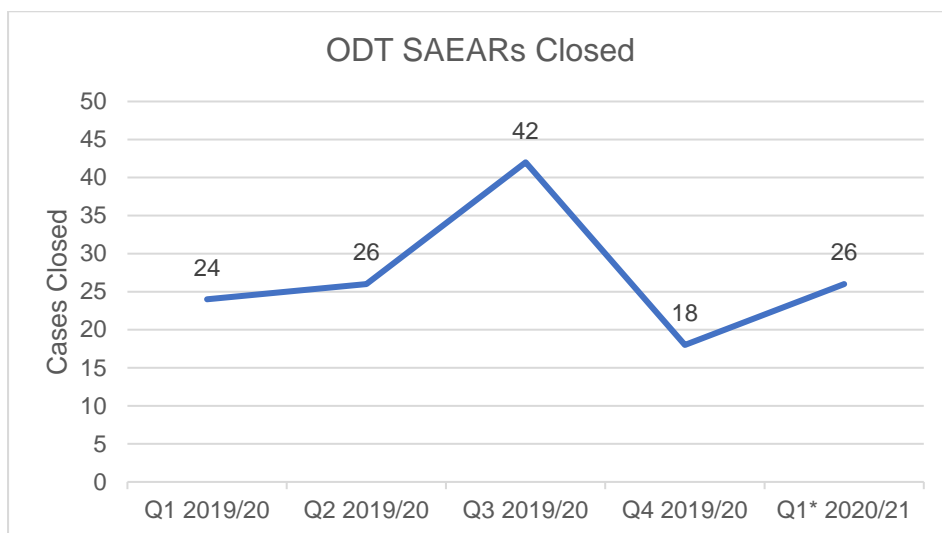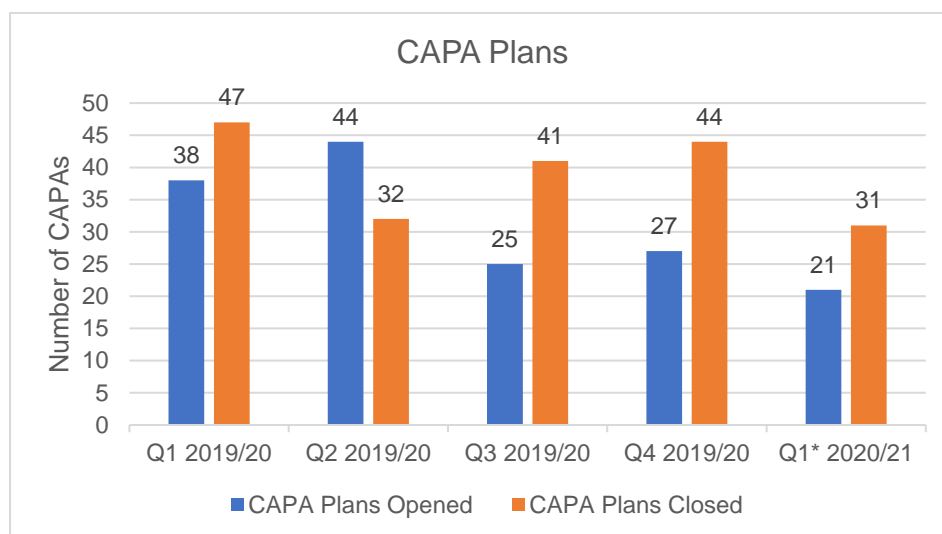

CAPA Plans

22. Figure 10 displays the number of CAPA plans opened and closed during quarter one, compared to previous quarters. The number of CAPA plans opened includes those opened as part of new licences offered.

23. A total of 21 CAPA plans were opened in quarter one. Eight CAPA plans were opened in the Human Application sector, ten were opened in the Post Mortem sector, one was opened in the Public Display sector and two were opened in the Research sector.

24. A total of 31 CAPA plans were closed in quarter one. 16 CAPA plans were closed in the Human Application sector, one closed in the ODT sector, 11 closed in the Post Mortem sector, one closed in the Public Display sector and two were closed in the Research sector.

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Figure 10: Number of CAPA Plans opened and closed during quarter

25. Table 5 shows all open CAPA plans at the end of quarter one and the length of time they have been open.

26. There were a total of 65 CAPA open plans at the end of quarter one. 26 CAPA plans have been open for less than six months, 18 have been open between 6-12 months and 21 CAPA plans have been open for longer than 12 months.

Table 5: All Open CAPA plans

Open CAPA Plans	Anatomy	Post Mortem	Human Application	Research	Public Display	ODT	Total
< 6 months	0	10	13	3	0	0	26
6-12 months	1	4	10	2	1	0	18
> 12 months	0	3	17	0	0	1	21
Total	**1**	**17**	**40**	**5**	**1**	**1**	**65**

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Website Analytics

27. These analytics compare website activity during quarter one of 2020/21 with quarter one of 2019/20, as this represents the best direct comparison.

Table 6: Audience Size

	2020/21	**2019/20**
Visits	50,554	53,793
Sessions	70,811	75,149

28. Overall traffic is down. This is against the trend, as in general we have seen yearly increases in audience size. For example, 2019 saw the number of users for the year increase by nearly 8% compared to 2018.

Table 7: Engagement

	2020/21	**2019/20**
Average time on page	2min 33s	2min 39s
Bounce rate	42.9%	41.7%

29. Engagement statistics both fell, but only by moderate amounts. There is no overall trend for engagement statistics over time, however we usually expect to see any fall in audience size to be met by an increase in engagement metrics. Bounce rate measures the percentage of site visits that arrive on a page on the website and leave without visiting another page. It is generally used as an engagement metric.

Popular Pages

30. There were no significant changes in which pages users were visiting on the website with two exceptions:
    - the number of people visiting the body donation page increased as a proportion of overall website visitors (9.7% compared to 9.0%).
    - there was a substantive increase in the number of people viewing the body donation FAQs. This increased from 0.17% of all page views last year, to 1.8% this year. This represents the continuation of increased visitors which began in October 2019 and does not represent a unique event during the period being reported.
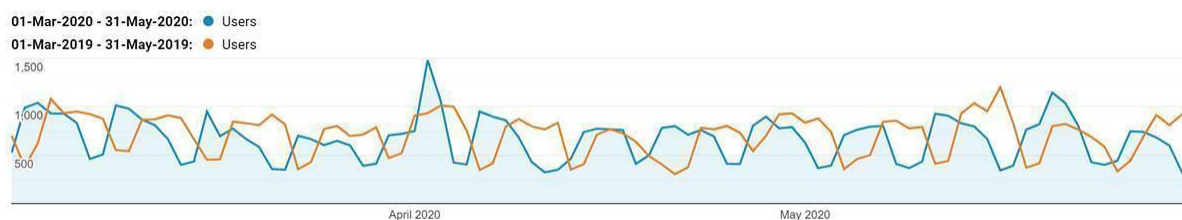
*Data period: 1st Apr – 28th Jun. May be subject to revision.

Additional notes

31. There was a significant spike in website visits on 2 April 2020 where 1497 people visited the website, compared to 932 for 2 April 2019.

32. This spike in traffic mostly originated from email referrals and coincides with a COVID-19 email sent to establishment staff which contained various links to the website.

Conclusion

33. Other than the spike in visits due to the COVID-19 email sent to establishment staff in April (as shown in the spike in site visits below), there is little to mark this period as being significantly different to any other.

Comparison graph (users over time)

01-Mar-2020 - 31-May-2020: ● Users
01-Mar-2019 - 31-May-2019: ● Users

*Data period: 1st Apr – 28th Jun. May be subject to revision.

Board paper

Date	16 July 2020	**Paper reference**	HTA (17/20)
Agenda item	8	**Author**	Louise Dineley
			Director of Data, Technology and Development
Protective Marking	OFFICIAL		

Business Continuity- Development Programme

Background

1. This agenda item provides an overview of the development plans over quarters two, three and four, including desk-based inspections. This item is supported by an annex of Power point slides which will provide the basis for the oral presentation which will be made at the Board meeting.

Decision-making to date

2. This content for this agenda item was approved by SMT on 9 July 2020.

Action required

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

HTA
Human Tissue Authority

Board paper

Date	16 July 2020	**Paper reference**	HTA (18/20)
Agenda item	9	**Author**	Richard Sydee
			Director of Resources

Protective Marking	OFFICIAL

Audit and Risk Assurance Committee Update

Purpose of paper

1. To provide the Board with an overview of the work of the Audit and Risk Assurance committee over the past 12 months.

Decision-making to date

2. This report was approved by the CEO on 8 July 2020.

Action required

3. The Board is asked to note the report and the opinions of ARAC on the governance processes within the HTA.

Background

4. The ARAC's formal role is to advise the Accounting Officer and Authority on:

    - the strategic processes for risk, control and governance and the Annual Governance Statement;
    - the accounting policies, the accounts, and the annual reports of the HTA, levels of error identified, and management's letter of representation to external auditors;
    - the planned activity and results of both internal and external audit;
    - the adequacy of management response to issues identified by audit activity, including external audit's audit completion report;
    - assurance relating to corporate governance requirements for the HTA; and

- the policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations.

5. There is an annual cycle of matters to consider, with ARAC's regular business focussing on assurance and risk management processes, as well as matters arising from internal and external audit work. At each meeting, the Committee received progress reports on all these areas.

Overview

6. This report summarises the Committee's activity during the year and gives the Committee's opinion on the HTA's risk management and internal control arrangements. The report forms part of the assurance processes, which support the Accounting Officer's Annual Governance Statement.

7. Membership of ARAC through the year has been:

- Amanda Gibbon (ARAC Chair);
- Bill Horne (Authority Member);
- Dr Stuart Dollow (Authority Member);
- Professor Andy Hall (Authority Member);
- Glenn Houston (Authority Member).
- Professor Gary Crowe (Authority Member)
- Dr Charmaine Griffiths (Authority Member)

8. During this period Bill Horne and Andy Hall stepped down from ARAC (February 2020) and Professor Gary Crowe and Dr Charmaine Griffiths joined as members of ARAC from its June 2020 meeting.

9. ARAC met three times in 2019/20. The Chief Executive, the Director of Resources, the Head of Finance and Governance and the HTA's external and internal auditors attended all meetings. Other Directors and staff attended to discuss particular risk areas that ARAC wished to explore, or other topics depending on ARAC's business. Colleagues from the Department of Health and Social Care also attend.

10. ARAC's terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular, by providing scrutiny to support the agreement of the Governance Statement.

Review of Committee effectiveness

11. The Committee reviewed its effectiveness in the period March 2019 to March 2020. This consisted of members responding to a series of questions relevant to ARAC at this time. The questions were:

a. What does ARAC do for the Authority?
b. Does the annual cycle of business cover all that we should?
c. Do ARAC papers cover what is needed? If not, what would be better?
d. Do we have sufficient expertise on the committee and in internal/external audit attendees properly to scrutinise as we should?
e. Do we have sufficient time in meetings?
f. Are the training sessions valuable? If you feel you need more training, what would that cover?
g. Do you feel able to raise everything you would like to discuss?
h. Is there anything we could do better?

12. The responses were very positive, with some minor suggestions for further improvement made.

13. ARAC members attended Department of Health and Social Care and National Audit Office (NAO) events, including networking meetings of audit committee members.

Risk Management

14. Strategic risks are reviewed by the Senior Management Team (SMT) on a monthly basis and are reported to ARAC at each meeting with the Risk Register being presented to the Authority quarterly.

15. During the 2019/20 business year, ARAC identified risk areas to explore in greater detail and relevant staff attended meetings to provide more information and assurance on:
    a. DI Engagement;
    b. Licensing Fees review; and,
    c. HTA Office relocation

16. The Committee reviews the strategic risk register at all meetings and discussed the updated risk register at its most recent meeting in June 2020 meeting.

Information and data security

17. Cabinet Office have required management boards to include a Senior Information Risk Owner (SIRO) since 2008, to ensure that priority is given to the protection of information and data. Within the HTA, the Director of Resources fulfils this role.

18. During this period ARAC has received regular reports on the transformation activity in this area, frequency and responses to IT and cyber incidents during the period as well as updates on the HTA's overall data and cyber security situation and policies.

19. ARAC has agreed with the thrust of the organisation's oversight and recommendations with regard to information and cyber security. Although the likelihood of an attack is low, the HTA continues to monitor the situation and takes all reasonable steps to protect against a cyber-attack, with an emphasis on making sure staff are aware of the risks and act accordingly.

20. Overall the SIRO considered that information risk was managed adequately. The Committee received a formal report from the SIRO at its last meeting.

Internal audit

21. During this period the Committee endorsed the Internal Audit strategy and plans for the year and monitored work progress. In total, five audits were undertaken across Critical Incident Management, Utilisation of Capabilities, Anti-Fraud Controls, Payroll & Expenses and Business Continuity.

22. Internal Audit gave "moderate" assurance that the HTA had adequate and effective systems of control, governance and risk management in place for the reporting year 2019/20.

External audit

23. NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2019/20 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

Assurance processes

24. During 2019/20, the Chief Executive met with HTA Directors at least monthly (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to share information, review progress against business plans, review strategic risk, and make necessary decisions.

25. The Committee believes that ongoing management review and communication, supported by the findings of audits and Departmental oversight give sufficient evidence to provide the Accounting Officer with assurance that the systems are sufficiently robust.

Governance Statement

26. The Governance Statement is a key part of the Annual Report and Accounts. It is signed by the Accounting Officer and explains how governance responsibilities have been discharged. The Committee considers that there is sufficient evidence of effective governance processes to support the signing of the Governance Statement. There are no material issues to be brought to the attention of the Accounting Officer or Authority.

Summary

27. The HTA's governance systems are well established and there is a commitment to making continuous improvements to them. The Committee is satisfied with the arrangements for risk management and the assurance processes.

Board paper

Date	16 July 2020	**Paper Reference** HTA (19/20)	
Agenda item	10	**Author** Matthew Silk	
		Head of Communications	

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Professional Stakeholder Evaluation 2020

Purpose of paper

1. To provide an overview of the latest professional stakeholder evaluation results, conducted in quarter four 2019/20.

2. To highlight the key emerging areas of development work related to the insight received.

3. To invite feedback from Members and answer any questions they may have on the results before they publish on the HTA website.

Decision-making to date

4. This report was approved by the CEO on 8 July 2020.

Action required

5. The Board is asked to note the report and the proposed next steps.

Background

6. Every two or three years the HTA commissions an evaluation of key stakeholders to better understand what they know, think, and have experienced in relation to the HTA's work.

7. These evaluations are a key measure of professional and public confidence in human tissue regulation, and help to inform the HTA's strategic direction whilst ensuring transparency and an intelligence-led, consultative, approach.

8. We will use results from the recent stakeholder evaluation exercise to make sure that our regulatory approach and engagement strategies remain fit for purpose and reflect the views and experience of our regulated establishments.

9. Previous to 2020, professional evaluations took place in 2010 and 2013; public evaluations took place in 2007, 2010, 2013 and 2017.

10. All previous evaluations are available on the HTA website here: [HTA > Corporate Publications > Evaluations.](#)

11. In quarter three 2019/20, heads of function and the senior management team (SMT) were engaged in the tendering and selection process of the research agency who would undertake the evaluation – Savanta ComRes – and an updated draft questionnaire was agreed to go into the field in quarter four.

Evaluation Response

12. The evaluation comprised two parts:

Online Survey

13. Savanta ComRes surveyed 518 stakeholders between 17 February and 9 March 2020 (compared to 362 in 2013).

14. 518 individuals out of a total sample of 3,028 contacts provided by the HTA responded to the survey, amounting to a response rate of 17.1%.

In Depth Interviews

15. Stakeholders were given an opportunity to opt in for telephone interviews at the end of the online survey.

16. 30 of these individuals were interviewed between 12 March and 16 April 2020, with five interviews per sector.

17. Interviews each lasted half an hour and were designed to explore and discuss stakeholder evaluations of the HTA in greater depth and detail.

Key Metrics

18. Overall, respondents were positive about their knowledge, understanding, interactions with, and experience of, the HTA.

19. The HTA scored positively across the three key metrics of:

- Knowledge – 96%
- Confidence in regulation – 94%
- Favourability towards HTA – 87%

20. Communications with, and how respondents would speak about, the HTA, were also net positive:

- Communications with the HTA – 78%
- Speak highly of the HTA – 69%

21. Favourable impressions appear to be primarily driven by perceptions of the HTA's professionalism in terms of being an effective and thorough regulator, and its perceived helpfulness in providing guidance and advice.

22. The most notable changes stakeholders had identified in their experience of the HTA in recent years were:

- More thorough regulation
- More supportive
- More accessible

23. At least nine in 10 respondents deemed the HTA to be effective in fulfilling its regulatory responsibilities.

Other Headline Results

24. The extent to which stakeholders understand what the HTA does is largely consistent across sectors; a majority think they know at least a fair amount from a high of 100% in the Anatomy sector, to a low of 83% in Public Display.

25. Interviews and survey data suggest stakeholders are aware of the HTA's statutory requirements. They often make unprompted references to these, and also rate them as highly important activities for the HTA.

26. Alongside being 'necessary', stakeholders also associate the HTA with being 'helpful', 'respectful' and 'thorough'.

27. Stakeholders mostly hold positive and balanced impressions of the HTA, often as a result of its professionalism, good engagement and helpful guidance.

28. The view that the HTA is authoritative and effective is more prevalent now than in 2013 although a minority suggest its approach can be inflexible:

   - Professional (94%), Authoritative (84%), and Expert (84%) were the words most commonly associated with the HTA.

   - Proportionate (63%), Modern (59%), and Flexible (51%) were the words least commonly associated with the HTA.

29. Favourability levels are broadly high and consistent by sector, from a high of 98% in the Anatomy sector to a low of 83% in Public Display.

30. A vast majority appear confident in the HTA as a regulator, some express uncertainty but this more often relates to regulation outside of their sector, from a high of 100% in the Anatomy sector, to a low of 91% in Public Display.

31. The scope of the HTA's regulation is considered as reasonable by a majority of stakeholders.

32. Most stakeholders suggest it is easy to know how to comply with the HTA's standards in their sector.

33. The revised codes of practice and standards appear to have largely had a positive impact on the tangible usage of the guidance in practice.

Potential Areas for Improvement and the HTA's Development Work

34. The HTA's Development Programme seeks to build resilience, agility, and overall sustainability through a programme of more significant organisational change activity, alongside a plan of continuous improvement.

35. There are two key areas that will be directly informed from the insight provided in the stakeholder evaluation, looking at how we develop and improve both our regulatory contact with establishments and a model for remote oversight and assessment. These are:

   - Relationship Management

- Format, and type, of inspection

36. A number of questions were included in the online survey to gauge the perceived impact of potential future developments in the HTA's approach and operating model. These were on the impact of:

- The introduction of a streamlined regulatory model with one point of contact / relationship manager for the whole organisation
- Shorter, more focused inspections
- The introduction of a publicly available rating or visible marking system to denote compliance
- Fewer onsite inspections
- More unannounced inspections

37. Respondents were most positive about the introduction of a "streamlined regulatory model" / "relationship manager" (81% positive).

38. This is something the HTA has been discussing internally and developing a model for how it might work, in particular, for a single organisation with multiple licences.

39. It also might serve to address negative feedback in the communications and engagement section of the survey, which was critical of the HTA's responsiveness to enquiries.

40. With the HTA's aim to be a right-touch, proportionate regulator, and engaging its authoritative voice to good effect, it is in line with the strategic aim of using the minimum necessary direct intervention to achieve compliance and improvement.

41. With the above in mind, it is key to ensure the best use of communications and engagement with establishments, as part of the HTA's regulatory toolkit, both as a pre-emptive measure to reduce the risk of shortfalls, and to avoid on over reliance on regulatory action.

42. Areas in which the HTA are looking to strengthen our regulatory communications based on the feedback from this survey are through:

- More sector focused communications and engagement
- More sector specific guidance for establishments
- Focusing on key areas where knowledge and understanding of the HTA's standards and guidance is reported as low
- Greater use of digital tools to engage with establishments, e.g. webinars, video meetings, Q&A sessions

43. The next most favoured option for potential future change was "Shorter, more focused inspections". This ties in, conceptually, with "more unannounced inspections" being the least positively received (29%).

44. The concept of more focused inspection links to our work - accelerated somewhat during the COVID-19 lockdown period - exploring how the HTA might conduct and undertake remote, regulatory activity and oversight.

45. It also related to our development work assessing how onsite inspection could happen with similar, or even greater frequency, as under the current model, but would focus on known areas of risk that are only transparent when onsite.

Next Steps

46. HTA to publish the stakeholder evaluation on its website alongside previous evaluation.

47. HTA to include a news item on the front page of the website to share with visitors.

48. HTA to add a news article to the July professional e-newsletter about the evaluation results and to thank all those who took part.

49. HTA to continue to use this insight to contribute to and direct work across the Development Programme.

HTA
Human Tissue Authority

Board paper

Date	16 July 2020	**Paper reference** HTA (20/20)	
Agenda item	11		
		Author Sumrah Chohan & Jess Porter	
Protective Marking	OFFICAL		

Living Donation Policy updates

Purpose of paper

1. The purpose of this paper is to update Board Members on three key areas in Living Donation:

    -   Emergency out of hours assessments;
    -   Novel cases and;
    -   Proposed new process for consideration of cases requiring decision by a panel.

Decision-making to date

2. This paper was approved by SMT on 2 July 2020.

Action required

3. Board Members are asked to note and comment on the proposals described in this paper.

Emergency out-of-hours assessments

4. During the November 2019 Board meeting, in response to concerns raised by some Members about taking part in the on-call rota for out-of-hours consideration of emergency living donation cases, the Board was presented with options for alternative arrangements.

5. Following feedback, the Executive undertook some further work. A paper was submitted to the SMT for consideration in June 2020 which outlined a new proposed approach.

6. This proposal was that the provision of out-of-hours assessment would continue, but that the assessment of these cases would be undertaken by Executive staff. Living liver donation decisions are already made by the Executive in office hours, and it is these cases which drive the demand for out-of-hours assessment.

7. A total of 13 Executive staff members are on the rota with a possibility for additional members of staff to join the on-call rota in the future once more individuals have been trained in the assessment of living donation cases. The rota is covered by staff who are trained in the assessment of cases. For any time taken out of hours to assess a case, staff will claim time off in lieu.

8. The revised approach was agreed by SMT on 4 June 2020. Work has been completed to update relevant SOPs and training has been delivered to all staff that are on the rota. The new arrangements came into effect on 1 July 2020.

Novel cases

9. An outstanding action point from the November 2019 Board meeting was to develop a policy for consideration of novel living donation cases.

10. Following detailed legal advice our internal policy HTA-POL-102, on the assessment of living donation cases, has been updated.

11. These will be treated as retained panel cases; all cases that meet the criteria of "novel" will be referred to panel for consideration. Please refer to the table on page five below for further details.

12. Once it has been established that the novel donation can be considered routine, using agreed criteria set out in the policy, cases will be considered by the Executive team.

13. The Policy has been approved by the Director of Regulation.

Proposed new process for consideration of cases requiring decision by a panel

14. Regulation 12 of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 require that for certain categories of living organ donation, the decision must be made by a panel of no fewer than three Members of the Authority.

15. Pre COVID-19, we continued to see a significant increase in the number of panel cases, leading to concern about the call this places on Members' limited time available for HTA business. In discussion between the Chair, DHSC and Board Members there has been a strong sense that the involvement in this level of executive decision making is inappropriate to the relative regulatory risks and creates a barrier to greater strategic focus by the Board across the whole of the HTA's regulatory remit.

16. We expect the volume of panel cases to return to pre COVID-19 levels by early 2021. This pressure may be compounded if there are delays in appointing new Members as current terms come to an end.

17. In the 2013/14 financial year, 262 cases were assessed by panel, compared to 382 cases in the 2018/19 financial year. This is an increase of almost 46% in cases requiring a decision by a panel. This figure is expected to continue to rise in line with NHSBT plans to maximise the potential of the national sharing schemes.

18. As Members are also aware, transplant centres are increasingly requiring decisions in less than ten working days, driven by factors such as theatre capacity, identifying suitable dates to meet the needs of all centres and patients, and NHSBT matching run deadlines. A reduction in time taken to assess panel cases would be welcomed by stakeholders.

19. In March 2020, we sought legal advice to ascertain whether there was any scope for the decision making by a panel of three Authority Members under regulation 12 to be delegated to the Executive. The advice confirmed there is not scope for delegation of the actual decision-making power in regulation 12(1) to the Executive. While we continue to make the case to DHSC to review this requirement, this remains unlikely in the short to medium term. However, the advice did provide alternative options for consideration of these cases to reduce the time spent by Members on assessing these.

20. The Executive has used the legal advice to develop a solution which will allow for a lighter touch and more timely approach to resolving the cases that require panel consideration but are now considered more routine, without fettering of the Board's discretion.

21. Paired/pooled donations, for example, were once considered to be novel and of greater complexity; these donations are now routine. These cases very rarely present a greater regulatory risk than directed donations and so the need for increased scrutiny has now reduced. It is these cases that have contributed the most to the significant increase in cases requiring a panel decision, as the national sharing scheme has become so successful.

22. Legal advice confirmed that there is nothing in the Act or the Regulations to prevent the panel of Authority Members appointing a competent person(s) to advise them and provide recommendations in relation to regulation 12(1), so long as the ultimate decision is made by the panel.

What will stay the same?

23. The Executive will continue to review every case before it is referred to panel as has always been the case. This is undertaken by the most experienced members of the Executive, the two Transplant Officers or the Transplant Manager. They will continue to liaise with the Independent Assessor and members of the clinical team to ensure that the evidence from the clinical work up has properly accounted for the regulatory requirements to be fulfilled.

24. Members will continue to have access to free text boxes in the "comments" section on CRM to ensure that it is possible to record the relevant documents that have been considered as part of decision making and input reasons for their decisions.

25. Cases will continue to be referred to panel each Wednesday, though the aim will be to do so my mid-morning at the latest.

What will change?

26. The Executive will provide a recommendation, supported by key facts, to the panel. This recommendation will summarise the key information required by law and suggest whether approval should be given. Panel members will be asked to review the recommendation and base their decision on this. Please see Annex A for an indicative template.

27. The recommendation will ordinarily be no more than half an A4 page in order to reduce the administrative burden. The recommendation will be uploaded to the "case notes" section of the case on CRM.

28. Relevant background documents will remain available for review, although there is no legal requirement for these to be reviewed by panel members. This proposed approach will allow Members to fulfil their statutory duty, allowing the discretion to review the full detail of a case, but generally reduce the time dedicated to this activity.

29. As mentioned at paragraph 18, a reduction in time taken to assess panel cases would be most welcomed by stakeholders. We are therefore suggesting that we reduce the time panels have to assess cases of paired, pooled and non-directed altruistic donations from ten working days to five working days. In 2019/20, 71% of panel cases were resolved within this timeframe.

30. A quality assurance check will be built into the system to provide assurance to Members that recommendations made by the Executive are supported by the documentation provided in the case. More work is required on the design of this quality assurance, but we anticipate sampling of an appropriate number of cases for checking.

For cases that require more input from Members

31. A separate process is proposed for those cases where the decision making has been retained by Members. This may be because they are more challenging, complex or novel to assess. This is to ensure we continue to focus additional scrutiny where it is most needed.

32. The table below sets out the proposed approach for each category type.

Category of donation	Reason for panel consideration	Process	Time frame in which to make a decision
Paired and pooled	Panel decision required by law	Executive to review and make recommendation to panel. Panel to review recommendation	5 working days
Non-directed altruistic	Panel decision required by law	Executive to review and make recommendation to panel. Panel to review recommendation.	5 working days
Cases the Executive is minded not to approve	Retained panel case	Executive to review and make recommendation to panel. All supporting documents available	10 working days
Economic dependence	Retained panel case	Executive to review and make recommendation to panel. All supporting documents available	10 working days

Directed altruistic donation with overseas donor	Retained panel case	Executive to review and make recommendation to panel. All supporting documents available	10 working days
Novel donations (as defined in HTA-POL-102)	Retained panel case (until established as routine when they will be considered by the Executive team)	Executive to review and make recommendation to panel. All supporting documents available	10 working days
Donor is adult lacking capacity	Panel decision required by law	Executive to review and make recommendation to panel. All supporting documents available	10 working days
Donor is a child (under 18)	Panel decision required by law	Executive to review and make recommendation to panel. All supporting documents available	10 working days

Next Steps

33. Subject to views of the Board, we would propose completing the design of the new system by early August, with training and implementation by the end of September 2020 at the latest.

Annex A

The template will include a mix of pre-filled text and drop-down boxes, in addition to text copied from the IA report where helpful.

Case TXXXXX   **Recommendation completed by:** Choose an item.

Information required by law		Comments
Category of donation	Choose an item.	
Donor: Any difficulties in communicating with the donor	Choose an item.	
Donor: Understanding of the nature of the medical procedure and the risk involved	Choose an item.	
Donor: Understands that consent may be withdrawn at any time before the removal of the transplantable material	Choose an item.	
Paired/Pooled cases **Donor:** Is aware of the implications of being a donor in the paired / pooled scheme and understands the process	Choose an item.	
Non-Directed Altruistic cases: **Donor:** Is aware of the implications of being a non-directed altruistic donor and understands the process	Choose an item.	
Donor: Any evidence of duress or coercion affecting the decision to give consent	Choose an item.	
Donor: Any evidence of an offer of a reward	Choose an item.	
SCOTLAND cases - Donor: Any relevant wider	Choose an item.	

implications arising from the intended donation, including the effect on any children or dependent relatives		
Recipient: Any difficulties in communicating with the recipient	Choose an item.	
Recipient: Any evidence of duress or coercion affecting the decision of the donor to give consent	Choose an item.	
Recipient: Any evidence of an offer of a reward	Choose an item.	
Approval recommended?	Choose an item.	