HTA
Human Tissue Authority

Ninety-fourth Meeting of the Human Tissue Authority

Date   5 November 2020
Time   10.00 – 12.05
Venue   Via Zoom

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 16 July 2020 meeting	HTA (21/20)
4.	Matters arising from 16 July 2020 meeting	HTA (22/20)
	Regular Reporting	
5.	Chair's Report	Oral
6.	Chief Executive's Report	HTA (23/20)
	- Strategic Risk Register	Annex A
	- Supplementary Data Annex	Annex B
	Change Programme	
7.	HTA Development Programme	HTA (24/20)
	Committees/Working Groups	
8.	Audit and Risk Assurance Committee Update	Oral
	Policy Updates	
9.	Living Donation Panel Case Recommendation	HTA (25/20)
10.	Risk Appetite Statement Update	HTA (26/20)
11.	Fee Proposals for 2021/22	HTA (27/20)
12.	HTA Contigency Arrangements in Response to COVID-19	(HTA (28/20)
	Any Other Business	
13.	Any Other Business	Oral
	- Board Member recruitment and end of tenure	
	Close	

![HTA – Human Tissue Authority logo]

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

Date	16 July 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) Nicolette Harrison (Director of Regulation) Amy Thomas (Head of Development) Nima Sharma (Board Secretary; minute taking)
	Observers
Apologies None	Jacky Cooper, Department of Health and Social Care (DHSC)

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

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; none were declared.	
Item 3	**Minutes of 6 February 2020 meeting [HTA 13/20]**	
	4. The Chair requested Members' comments on the minutes for factual accuracy. There were no further comments made.	
	5. The Board approved the minutes.	
Item 4	**Item 4 Matters arising from the 18 July 2019, 7 November 2019 and 7 May 2020 meeting – HTA (14/20)**	
	6. The Chair informed Members that actions two and five would be dealt with under agenda item 11.	
	7. Nicky Harrison was asked to provide an update on actions one and three in the matters arising log. Nicky confirmed that Louise Dineley had emailed Members with some further information on SAEARs in HA sector and that fuller accounts on trends would be provided at item 7. In relation to action three Nicky confirmed that further discussion with Louise Dineley, in the use of statistical process control for data analysis would be explored as part of our data development plans.	
	8. The Board noted the content of this item.	
Item 5	**Chair's Report [Oral]**	
	9. The Chair provided an update on the Stakeholder meetings attended in quarters four of 2019/20 and quarter one, as well as the plans for upcoming meetings. She confirmed that there was considerable interest from other Chairs and Chief Executives in working collaboratively with the HTA and follow up meetings have been requested by partners. Greater collaboration is a theme of her objectives as set by the Department of Health and Social Care.	
	10. She informed Members that she met with Lord Bethell, Minister for Innovation, who is very much interested in the work of the HTA, in particular our work on COVID-19 and mortuary licensing.	

	11. She confirmed that Bill Horne's tenure had been extended for up to a year while a recruitment exercise takes place. There were no further updates on whether the Members appointed by the Secretary of State in England would have their terms extended. Jacky Cooper informed the Board that the decision on short term extensions was currently with Ministers.	
	12. Members were also informed Bishop Graham Usher had taken the decision to step down as HTA Board Member early with a date yet to be determined. Graham was thanked for his contribution to the Board.	
	13. She also highlighted that there would be further discussion around the chairing of working groups which would be linked with the internal audit of the HTA's corporate governance which will commence shortly.	
	14. The Board was informed that the HTA received a letter from the Department of Health and Social Care thanking the HTA for working at pace on temporary mortuary licensing arrangements as well as the implementation of deemed consent legislation.	
	15. The Board noted the content of this update.	
Item 6	**Chief Executive's Report [HTA 15/20]**	
	16. Allan Marriott-Smith presented this item.	
	17. Allan summarised the report and confirmed that a decision had been taken that inspections would not resume in quarter three. The HTA is currently working towards recommencing inspections of establishments in the human application sector from January 2021.	
	18. He emphasised that there are a number of considerations to be satisfied before resuming inspections, such as travel safety, health and safety protocols, personal and protective equipment as well as the regional infection rates. He also stated that a decision on return to inspection for the sectors regulated under the Human Tissue Act 2004 would be taken in quarter three.	
	19. Members were informed that Nicky Harrison would be leading on a piece of work to evaluate the need to return to inspections relative to the risks posed by the pandemic.	

	20. Members were also informed that the HTA is prepared for the end of the EU exit transition period, with work around import and export licence requirements underway.	4
	21. Richard Sydee provided an update to the Board on the HTA's quarter one financial position. He confirmed that the position was balanced with a spend within budget. Uncommitted budget would be directed to priority development projects.	
	22. Members were informed that the HTA could absorb up to around a five per cent reduction in licences if HTA establishments exit the market. The HTA would assess the likely impact of reduced licensing by September.	
	23. Members highlighted that there was a discrepancy on the table presented on page five of the report. Richard Sydee confirmed that this would be corrected post meeting.	
	24. The Board congratulated the Executive on HTA accreditation under the Race at Work Charter and Disability Confident Charter.	
	25. The Board noted the content of this report.	
Item 7	**Business Continuity- Regulatory Update [HTA 16/20]**	
	26. Nicky Harrison presented this item to the Board.	
	27. She asked the Board for any specific questions and reiterated that quarter one had been challenging and that the HTA had maintained a full range of regulatory activity, except for site visit inspections.	
	28. The Board highlighted their concerns over a reduction in the number of HTA Reportable Incidents reported to the HTA during the pandemic. Nicky confirmed that it is unusual for there to be a decline in the number of incidents reported during a time of excess deaths and therefore the HTA would be working with the sector to ensure that no under reporting is taking place.	
	29. Nicky informed the Board that the resourcing of the Regulation directorate had been adjusted to deal with changed demands.	

	An example of this, was a Regulation Officer who had been moved into a Regulation Manager role to support the increased activity in the post mortem sector.	5
	30. The Board noted that there was a large proportion of corrective and preventative actions plans open in the HA sector over a period of 12 months. Nicky highlighted that some of the plans were still open awaiting the completion of further work, to be undertaken by the HTA in collaboration with the MHRA, relating to environmental monitoring. Nicky reassured the Board that the licensed establishments were still operating compliantly with little impact on their activities.	
	31. The Board noted the content of this paper.	
Item 8	**Business Continuity – Development Programme [HTA 17/20]**	
	32. Louise Dineley presented this update to the Board.	
	33. Louise informed the Board that there were six themes identified as priorities that are currently being scoped. She referred the Board to the final slide of the presentation which provided an illustration of what a future operating model at the HTA may look like.	
	34. She provided the Board with an insight into the model and how this would work in principle, highlighting that site visits would remain a key part of what the HTA does. She emphasised that the HTA should also focus on strengthening its use of data along with relationship management.	
	35. The Board supported the direction of travel set out in Louise's presentation and highlighted the centrality of regulating the consent provisions of human tissue legislation in any future operating model.	
	36. The Board also asked the Executive to take into consideration public expectation of inspection as a key regulatory tool in deciding when to return to site visits, and the level of oversight required by the HTA if return to inspections is not possible.	

	37. The Board emphasised that there may be a danger of the HTA not maintaining appropriate boundaries with establishments if the HTA focusses its resources on relationship management. 38. The Board noted the content of this paper.	
Item 9	**Audit and Risk Assurance Committee Update [HTA 18/20]**	
	39. Amanda Gibbon provided an update to the Board on this item. 40. She informed the Board that at the meeting in June the annual report and accounts were signed off and subsequently laid before parliament. 41. Amanda confirmed that Anthony Stanley, Audit Manager for Government Internal Audit Agency was stepping in following Jeremy Nolan's departure in the short term until permanent arrangements to appoint a new Internal Audit Director are made. 42. Amanda thanked Richard Sydee and Morounke Akingbola for their work to get the accounts complete within the normal timeframe in the face of several obstacles. 43. The Chair acknowledged a number of changes in the membership of ARAC. She thanked Bill Horne and Andy Hall for their work as Committee Members. The ARAC Committee Members also acknowledged the amount of work undertaken by Amanda Gibbon during her tenure as chair of ARAC. She was thanked by everyone. The Board was reminded that, Gary Crowe will take over chairing ARAC in October. 44. The Board noted the content of this paper. **Action 1:** To circulate the Annual Report and Accounts to the Board for information (Action complete).	**NS**
Item 10	**Professional Stakeholder Evaluation [HTA 19/20]**	
	45. Matthew Silk presented this paper to the Board. 46. He confirmed that the results were heartening and that largely positive comments were made about the HTA by stakeholders.	

	47. The Board was informed that there were some areas for improvement identified in the evaluation, such as timing of response to enquiries and being proportionate and flexible.	
	48. The Board suggested that the outputs from this evaluation should be discussed at the next Stakeholder and Fees Group meeting.	
	49. The current chair of ARAC suggested that a deep dive at the next meeting could be undertaken, looking more closely at the data.	
	50. The Board suggested that the Executive seek feedback on how the HTA have managed communication with the sectors during the pandemic.	
	51. The Board noted this update.	
	Action 2: The outputs from the Professional Stakeholder Evaluation to be added to the agenda for the next Stakeholder Fees Group meeting.	**MS**
	Action 3: Executive to decide whether an examination of the data from the Professional Stakeholder Evaluation is an appropriate topic for an ARAC deep dive.	**RS**
Item 11	**Living Donation Policy Issues [HTA 20/20]**	
	52. Jess Porter presented this paper to the Board.	
	53. She asked the Board for their views on the proposed new process for the consideration of cases requiring panel decision.	
	54. The Board asked whether the Executive had explored whether this would create further work for the Executive in completing the checklist. They were given assurances that it would not.	
	55. Overall, the Board were in support of the proposed change, although some expressed concerns about meeting the full regulatory requirements if they did not see all the material. A trial of the proposed process was agreed to see how this would work in practice.	

	56. The Board suggested that the approval timeframes should be left as 10 working days. The Board asked the Executive to review this in two to three months to identify whether five working days is realistic in practice. 57. The Board agreed that the Executive should provide an interim report, covering a three to six-month period, on the new process for the Board to review. **Action 4:** A paper providing an update on the new process for consideration of panel cases to be brought to the November meeting.	**JP**
Item 12	**Any Other Business**	
	58. The Chair asked the Board, Executive and observers if there was any other business. 59. Lorna Williamson confirmed that she had sent a note around to Members that Mike Osborn will become President of RCPath from November and would be stepping down as a representative on the Histopathology Working Group (HWG). The Board highlighted that a suitable RCPath representative would need to be identified to replace Mike Osborn, and Lorna Williamson agreed to ask RCPath to provide one. She asked the Board and Executive whether the HWG should be re-instated along with other working groups. The Chair requested for Allan to bring back a proposal about when these should recommence. 60. There was no other business raised. **Action 5:** Allan Marriott-Smith to take a decision on re-instatement of stakeholder groups in light of the internal audit on corporate governance.	**AMS**

Date of next meeting- 5 November 2020

HTA Board Meeting - Matters Arising from July

Meeting	Action	Owner	Update
July 2020	Action 1: To circulate the Annual Report and Accounts to the Board for information (Action complete).	NS	Document circulated August 2020.
July 2020	Action 2: The outputs from the Professional Stakeholder Evaluation to be added to the agenda for the next Stakeholder Fees Group meeting.	MS	This has been added to the draft agenda for the next SFG meeting.
July 2020	Action 3: Executive to decide whether an examination of the data from the Professional Stakeholder Evaluation is an appropriate topic for an ARAC deep dive.	RS	Ongoing.
July 2020	Action 4: A paper providing an update on the trial of the new process for referral of panel cases to be brought to the November meeting.	JP	This is tabled for the November 2020 Board meeting.
July 2020	Action 5: Allan Marriott-Smith to take a decision on re-instatement of stakeholder groups in light of the internal audit on corporate governance.	AMS	To be covered in the CEO report for the November meeting

Board paper

Date	5 November 2020	**Paper reference**	HTA (23/20)
Agenda item	6	**Author**	Allan Marriott-Smith
			CEO

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Chief Executive's Report

Purpose of paper

1. This paper gives an overview of performance at the end of quarter two.

2. It provides the Board with an account 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 July.

3. Work continues to ensure that we balance our regulatory responsibilities, our development goals and respond to a fast-changing environment in an agile way, in the face of several concurrent externally driven risks.

General overview and strategic risks

4. No site visits were undertaken in quarter two. The HTA had indicated an intention to reinstate some site visit inspections in the HA sector in quarter four. However, in view of the continuing nationwide efforts to manage the risks of the pandemic and the concurrent risk of winter flu pressure alongside the end of the transition period, SMT has taken the decision to suspend inspections until further notice. This situation will be kept under regular review.

5. Other regulatory activity was maintained over the quarter.

6. During quarter two, the HTA has made excellent progress on the Development Programme and other change projects. Significant progress has been made on plans

   to undertake safe site visits; virtual regulatory assessments; producing a framework to licence funeral directors; plans for the office move; the HTA website redevelopment work and UK transition.

7. In its assessment of risk in September, the senior management team concluded that all six risks had stabilised over the summer. The Strategic Risk Register is included as Annex A to this paper.

8. SMT wish to draw the Board's attention to two areas of strategic risk. Risk one ***failure to regulate in a manner that maintains public safety and confidence and is appropriate*** is considered, on balance, to be stable. Although the HTA is not currently undertaking site visits (and, consequently, has removed this as an opportunity to identify and correct shortfalls against standards), we continue to deploy a range of other regulatory tools. In addition, we have made good progress on developing a model for virtual regulatory assessments (VRAs) which are being deployed in the HA sector in quarter three.

9. Risk four ***failure to utilise people, data and business technology capabilities effectively*** has been entirely rewritten to reflect the action that has been undertaken to address the recommendations of the internal audit on utilisation of capabilities. The Board is asked to note the action that has been taken to mitigate risks in this area.

Quarter two regulatory overview

10. Core regulatory activity was maintained at a high standard during quarter two. Members should note Annex B to this paper, which sets out the key metrics associated with this activity.

11. Although the decision has been taken not to return to site visit inspections until the external situation stabilises, work was completed in October on how the HTA will undertake safe site visits when this is appropriate - and includes the risk assessments that will be required, considerations about behaviours on site, and personal protective equipment (PPE) requirements.

12. There are currently two projects underway to develop our virtual regulatory assessment capability. The first is a pilot in the HA sector which will begin in quarter three. As part of this project, ten assessments will be undertaken in the quarter: seven informed by a risk assessment based on our data collection in the first half of the year and three controls to establish the quality of this assessment.

13. The second project looks to establish a virtual regulatory assessment model in the other sectors regulated by the HTA. This second project will be informed by lessons from the HA sector, and both projects will inform, and be informed by, work being undertaken in the Development Programme (in particular the projects on the future operating model and on better use of data and intelligence).

14. Work has continued during quarter two to support Public Health England (PHE) in understanding and meeting the regulatory requirements for removal of material from the deceased to support its COVID-19 surveillance programme. Over the quarter, the HTA has also developed a streamlined regulatory model for the licensing of funeral directors to allow material for testing to be removed at their premises. The first such licence was issued in quarter two.

15. Members will be aware that a case which the HTA referred to the police for investigation gained significant media attention. This case related to the storage of relevant material on unlicensed premises.

16. The Organ Donation and Transplantation Team was involved in a case that was referred to the Court of Protection. On 23 June, the Court ruled on a case of an adult lacking capacity, donating peripheral blood stem cells to her mother. This was the first case of its kind since the HTA's inception. We had advised the Trust involved that a Court of Protection referral would be required. The Judge ruled that it was "overwhelmingly in the donor's best interest to participate in the proposed programme and donate her stem cells for the benefit of her mother".

17. Work has continued in quarter two on piloting the streamlined process for living organ donation assessments in cases requiring a panel decision. The outcome of this work is presented in paper HTA (25/20).

Quarter two - Development Programme overview

18. Good progress has been made on the projects within the Development Programme. More detail on the Programme is provided in paper HTA (24/20).

Quarter two - other change projects

19. The HTA has maintained its readiness for a range of eventualities at the end of the UK transition period. SMT reviews preparedness at its meeting each week and has provided assurances to Department of Health and Social Care (DHSC) that we stand ready to advise and support our stakeholders.

20. Good progress has been made on the website redevelopment project. During quarter two we received excellent feedback from NHSX on the evidence we had assembled to demonstrate that the HTA's development in this area will meet user needs.

21. Although it is, at present, unclear when the HTA will permit regular office-based working, we have continued to prepare to take over the lease at the new premises in Stratford and vacate the office in Victoria. Although there have been some delays in the development of the Stratford site, the building will be available for occupation in early November.

22. During October, we made arrangement for staff wishing to attend the Victoria office to do so, to carry out relevant housekeeping by clearing lockers, collecting personal belongings and scanning relevant documents. During each visit a Head or SMT member was also in attendance to ensure social distancing was maintained. Each member of staff was provided with relevant health and safety training prior to the attendance and carried out a personal risk assessment.

Finance

Financial position for Q2 2020/21

Table one: summary position

HUMAN TISSUE AUTHORITY
Summary Management accounts for the period
For the Six Months Ending 30 September 2020

| | Year-to-date | | | | |
| | Actual | Budget | Var | Var | Forecast |
	£'000s	£'000s	£	%	£'000s
INCOME					
Government Grant in Aid	374,000	322,000	52,000	(11.96%)	771,000
RF RDEL	102,820	102,820	0	0.00%	205,660
Licence Fee income	3,963,187	3,937,480	25,707	0.65%	3,963,187
Devolved Governments	133,572	138,448	(4,876)	(3.52%)	133,572
Rental income	183,895	185,000	(1,105)	(0.60%)	368,895
Other income	23,392	23,475	(83)	(0.35%)	46,867
TOTAL INCOME	**4,780,866**	**4,709,223**	**71,643**	**(0.66%)**	**5,489,181**
OPERATING COSTS					
Staff costs (salaries etc)	1,570,558	1,620,496	(49,938)	(3.08%)	3,129,624
Other staff (exc inspection)	63,674	33,960	29,714	87.50%	133,874
Authority costs	71,955	85,539	(13,584)	(15.88%)	150,473
Inspection costs	(318)	0	(318)	0.00%	14,242
LODT costs	307	0	307	0.00%	1,500
Communication costs	11,501	5,238	6,263	119.57%	20,511
IT and Telecom costs	201,271	161,230	40,041	24.83%	416,956
Office and Administration	7,586	9,990	(2,404)	(24.07%)	17,844
Other costs	29,247	31,920	(2,673)	(8.38%)	113,730
Legal and Professional costs	63,881	46,500	17,381	37.38%	140,381
Accommodation	416,227	406,750	9,477	2.33%	822,977
Non-cash costs	39,869	102,830	(62,961)	(61.23%)	264,279
Development Programme	0	0	0	0.00%	262,790
Total operating costs	**2,475,757**	**2,504,453**	**(28,696)**	**(1.15%)**	**5,489,181**
Net Income/(expenditure)	**2,305,109**	**2,204,770**	**100,339**	**(0.11%)**	**0**

23. Table one (above) provides a summary position at the end of quarter two of the 2020/21 financial year: a year to date net deficit against budget of **£2k.** This is a reduction of £17k as reported at the end of quarter one. A breakdown and more detailed explanation are given below.

Income

24. Table two shows the breakdown of income to date. The variance to budget within our Grant in aid **(£52K)** is the result drawing down a higher sum this quarter with the remaining balance being spread over quarters three and four.

25. We have billed all sectors this quarter and our licence fee income is above budget by **£26k,** largely due to income from application fees **(£40k)** offset by minor shortfalls in fees across all sectors except Anatomy.

26. The small variance of £5k against income from devolved governments is due to a small inflation increase that was not billed as part of our COVID-19 response.

Table two: income summary

Human Tissue Authority

Income Summary
For the Six Months Ending 30 September 2020

	Year to Date			
	Actuals	**Budget**	**Variance**	
	£	**£**	**£**	**%**
Grant In Aid				
GIA	374,000	322,000	52,000	16.15%
Non Cash cover	102,820	102,820	0	0.00%
Sub-Total	**476,820**	**424,820**	**52,000**	**12.24%**
Licence Fees				
Application Fees	39,890	0	39,890	0.00%
Anatomy	104,780	102,230	2,550	2.49%
Post Mortem	1,285,856	1,301,095	(15,239)	-1.17%
Public Display	20,908	22,990	(2,082)	-9.06%
Research	720,038	717,705	2,333	0.33%
Human application	1,477,130	1,483,100	(5,970)	-0.40%
ODT	314,585	310,360	4,225	1.36%
Sub-Total	**3,963,187**	**3,937,480**	**25,707**	**0.65%**
Other				
Other income (Rent)	183,895	185,000	(1,105)	-0.60%
Other income (Secondees)	23,392	23,475	(83)	-0.35%
Devolved Assemblies	133,572	138,448	(4,876)	-3.52%
Sub-Total	**340,858**	**346,923**	**(6,065)**	**-1.75%**
Total Income	**4,780,866**	**4,709,223**	**71,643**	**1.52%**

Expenditure (by exception)

27. **Staff costs (salaries)** - year to date we are under budget by **£50k** (2.95%) and this is mainly due to vacancies being carried, mainly at Manager level, within the Regulation Directorate.

28. **Other staff costs** – are overspent against budget **(£30k)** which is largely due to overspends within recruitment (£15k), training (£13k).

29. **Inspection costs** – there has been no expenditure in the first half of the financial year due to deferment site visits until further notice

30. **Board costs** – are underspent (£14k) a result of very limited travel by Members as a result of remote working due to COVID-19 pandemic.

31. **Communication costs** - are over budget by **£6k.** Costs relating to Code of Practice publication costs (£2k) and online survey costs (£5k) which are offset by small underspends elsewhere.

32. **IT and Telecom costs** – are over budget due to the inclusion of subscription costs relating to O365 (£15k) which overlap the end of the current contract, also additional support (£13k). Maintenance costs are over budget (£10k) due to some unbudgeted elements, and an £8k overspend in IT consultancy is due to profile of the budget where these costs were profiled later in the year. These are offset by an underspend of (£7k) within consumables that reflects the lack of low value IT consumables needed during this period of remote working.

33. **Legal and professional costs** – are overspent by **£17k** 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.

34. **Accommodation costs** – (£9k) over budget due to additional service charge costs relating to 151 Bucking Palace Road not budgeted.

35. **Non-cash costs** – these are the costs of depreciating or amortising our assets. These are (£7k) over budget, offset by release of part of provision (£70k) made last year for staff travel costs. This reversal was made based upon indicative information around HTA staff's future working patterns. It will be reviewed again at quarter three once this has been finalised.

Forecast outturn

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

37. Currently we are forecasting a balanced position. This takes into account all known plans, the reduction in site visits and the lower resulting costs they bring. Work pertaining to the Development Programme will be funded from the current surplus (£263k) that is shown against the line of the same name. Approximately £200k of this has been allocated to projects and will be moved to budget lines once final quotes are received.

38. The utilisation of these funds will be overseen by SMT and monitored by the finance team over the remainder of the year.

Other key performance indicators

Debtors

39. Our outstanding debtors as at 30 September 2020 is **£4.1m** compared with **£2.6m** in the same period last year. The significant increase is due to deferment of billing the HA Sector to September.

40. The outstanding amount is represented by **592** accounts of which:

    a. **19** (£45k) – no movement from quarter one and they 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.
    b. **20** (£313k) relate to the 2019/20 business year. The most significant account is that of outstanding rent and increases suffered by the HTA and their shared invoice – we have received confirmation that these invoices have been approved for payment. As above, the remainder were contacted in advance of the September billing run and will be contacted throughout quarter three.
    c. The remaining **553** accounts are invoices billed on 22 September to all sectors and will not be pursued until 29 October as part of our credit control process.

41. Below is a breakdown by sector of the outstanding debts as at 30 September 2020.

Table Three: Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	312	£2,814,201.00	69%
Government Bodies	23	£129,500.00	3%
Non Government Bodies	257	£1,152,054.00	28%
Total	**592**	**£ 4,095,755.00**	**100%**

Financial risks

42. 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.

43. The impact of COVID-19 is noted and a new, albeit medium to low proximity, risk of running out of cash has been added to the key risks table. Other mitigation, not included under controls, is that the DHSC would fund any shortfall.

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 the 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

COVID-19 response

44. All HTA staff continue to work from home. From a people perspective, during quarter two, the remote working practice across the HTA stabilised. Line Managers were encouraged to conduct regular assessments of general wellbeing and the impact of home working on teams and individuals.

45. The supplementary guidance on flexible working was regularly promoted. However only two members of staff requested work patterns that fell within this guidance. Various innovative solutions were offered to enable staff to continue to deliver their objectives whilst also managing home schooling, caring responsibilities and their own mental and physical health. With schools returning at the beginning of September this supplementary guidance was withdrawn with no adverse impact to staff or deliverables.

46. As it became clearer the pandemic would continue through the winter months, further requests for IT equipment and ergonomic office set up were received and met.

47. As SMT made the decision that the HTA would not resume any form of office-based working this calendar year, the Head of HR and the HR Manager spoke to each member of staff individually to ascertain, appetite for a one off visit to the 151 BPR office to retrieve personal items, and the need for documentation scanning. The one-off visits have been completed.

48. Remote working contract addenda have been issued to those staff who indicated a wish to work predominately from home when office-based working resumes. We have asked to sign the revised contracts by the end of October and remote working contracts will come into effect on 1 January.

Change

49. A Change Manager was recruited to support the Development Programme and guide staff through the changes planned over the next six months. Understanding Change and Preparing for Change training sessions have been delivered to SMT and Heads of Department. More training sessions are planned for all staff.

Wellbeing

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

51. For winter preparedness, staff have been encouraged to think about their resilience over the coming four to six months, what they might need to do differently to manage the physical and mental health in the face of fewer daylight hours and an assumed increase in COVID-19 infection rates. Various suggestions have been added to the Wellbeing page of Wave.

52. Additional material, links and videos to support healthy living and working practices which include mindfulness and personal resilience have also been added to Wave.

53. The Diversity and Inclusion page on Wave highlights national and international events and encourages awareness and celebration of multicultural festivities.

Pulse survey

54. A second Pulse survey was conducted in July to better understand the impact of remote working and the level of staff engagement with the Development Programme. The survey had an 85% response rate (the same as for the April pulse survey) and the results ranged between 81% and 95% positive for each of the 5 questions, which is a slight improvement on the April survey of 79%- 83% positive.

Training

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

- Developing remote teams for line managers
- Remote Auditing
- Data and Analytics for Managers
- The Lunch and Learn programme covered topics including COVID-19, Governance at the HTA and Human Factors.
- A Learning and Development schedule is being developed to support the Development Programme.

Personal Development Plans (PDPs)

56. All staff have completed their mid-year reviews and the signed PDP's have been sent to HR for personnel files.

57. A Competency Framework has been developed to guide the behaviours that form part of measures within the PDP objectives and a Capability Framework has been approved by SMT both will be rolled out quarter three.

Recruitment and Retention

58. We have recruited an interim EU Transition Project Manager and an interim Change Manager. Further recruitment plans include an interim Communications Lead for the Development Programme, an interim Business Planning and Reporting Manager and an interim Customer Service Administrator.

59. There was one resignation in quarter two.

Virtual HTA All Staff Away Morning

46. The Virtual HTA All Staff Away Morning took place on the 16 September. The focus of the morning was the HTA's Development Programme specifically engaging staff on the HTA's priorities for the next six months. The session was interactive using a polling system to gain an insight into the current understanding of the Development Programme, the status of site visit inspections, the office move and the changes to staff contracts.

Remuneration Committee

47. The Remuneration Committee met on 2 October and agreed a 2.3% pay increase for all eligible staff which would be back dated to August this year.

Other issues

Quarter One Accountability

48. 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.

49. The HTA's sponsor wrote to confirm there were no concerns with our performance in quarter one and gave positive feedback on our performance in the first three months of the year.

Publication Scheme changes

50. In line with the HTA's commitment to ensure transparency, the HTA publish details about the volume and nature of incidents that are reported to us. Previously, we published descriptions of incidents following freedom of information requests and as part of standard reporting to the Board on regulatory activity.

51. From the 1 July the way in which information relating to the publication of HTARIs and SAEARs changed. A quarterly report detailing the volume and nature of closed incidents is now published on our website. This report will include information for all incidents that have been investigated and closed in the quarter.

Internal Audit

52. Internal Audit presented their paper to the Audit and Risk Assurance Committee on 15 October and issued the Cyber Security audit report which was given a moderate assurance.

53. An audit focussing on Corporate Governance: Effectiveness of Stakeholder Engagement was conducted over the summer period. The Executive will be developing a response to the Corporate Governance audit recommendations (including on the future of Working Groups). These will be presented at the next meetings of ARAC and the Board. In the interim, stakeholders will be managed by the Executive.

Freedom of Information requests

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

Complaints

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

HTA Strategic Risk Register
September

The easing of restrictions associated with the COVID19 pandemic in early July , followed by the application of various additional regional lockdown measures, has brought an increasing realisation of the need to develop and manage expectations about future plans in the context of adapting to a new normal of living with Covid, rather than a return to normal. The senior team is therefore continuing to balance a number of competing pressures: when and how to safely return to undertaking site visit inspections (and the form these should take), balancing resources between regulatory delivery and development, the work associated with UK Transition, given greater certainty now that there will be no extension of the transition period, and the office move. Operating in this highly uncertain and fast-changing context increases the risk of sub-optimal allocation of resources and so we are also increasingly focusing on greater depth and clarity of business and resource planning to ensure that resources are applied to areas of greatest risk. As of September, we feel that we have the right actions and plans in place to mitigate/reduce current risks. There is an element of acceptance of some risks for a period after which a review of plans will be conducted.

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are: *failure to regulate appropriately* - the score for which increased as a result of the continuing absence of site visit inspection as part of our regulatory toolkit during this initial phase of the pandemic 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 ongoing temporary removal of routine site visit inspections 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 response to changing Covid-related government restrictions whilst also seeking to take advantage of this opportunity to quickly take forward long-planned strategic change through the development programme. The organisation has adapted well to this new working environment and is developing new regulatory tools to supplement our existing non-site visit activity, that will allow continued oversight of our sectors.

Other notable risks: Understanding the impact and resource required to deal with UK Transition and the medium to long-term impact of the UK's departure from the EU is proving challenging. Horizon scanning for emerging issues and liaison with DHSC remain a key focus.
Progress on other development activity has continued to gather pace using the additional funds available this year from the cessation of site visits and a recruitment freeze that are being invested for optimum benefit this business year. In particular, this includes work to support our office move and to build a foundation for future strategic development. Work is now commencing on these development priorities.

Risk	June 2020	July 2020	Aug 2020	Sept 2020	Comments
1 - Failure to regulate appropriately *(Risk to Delivery a-d & f and Development a-d)*	→	→ **10**	→ **10**	→ **10**	Whilst we have a good regulatory framework for normal times, with a strong assured position on our key regulatory processes from an Internal Audit review within the past 18 months. We coped well with the novel challenges and intensity of increased activity in the PM sector during the peak of the pandemic but continue to face new challenges arising from this new context, particularly the suspension of one key regulatory process, site visits, across all sectors since mid-March. Activity in the PM sector is now stable and in good control and we continue to use all other regulatory tools and processes. We have been developing remote risk profiling and inspection processes through the virtual regulatory assessment work, prioritising the HA sector where we have undertaken a targeted survey of all establishments that is now being followed-up with discrete interventions. As government restrictions are starting to be eased, albeit this varies by region, we are planning on how to safely undertake site visits, again prioritising the HA sector. Our inability to meet our legal obligation to undertake biennial site visits in this sector since mid-March 2020 is being managed as an issue, of which the Board and DHSC sponsors are aware. The continuing absence of site visit inspections by the HTA may result in an increase in this risk, or perception of this risk by external stakeholders, although this may vary by sector. We anticipate moving from developing and assessing the viability of a virtual model to pilot during Quarter 3 and build on in the remainder of the business year. A decision on safe site visits will be taken in October reviewing government advice at that time. These activities help mitigate this risk. SMT believe this risk is stable in September 2020.
2 - Failure to manage an incident *(Delivery, Development and Deployment)*	→	→ **6**	→ **6**	→ **6**	We have plans in place to manage an incident and are reviewing and responding to the final reports from the internal audit review of our Business Continuity and Critical Incident Management arrangements, which provided moderate levels of assurance in both areas. Actions will be discussed with ARAC in due course.

The HTA response to managing the impact of the pandemic using these existing plans has been a significant stress test of their adequacy. They have not so far 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 is stable in September 2020. |
| **3 - Failure to manage expectations of regulation** *(Risk to Delivery e and Development c)* | → | → **12** | → **12** | → **12** | 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 identify perimeter issues.

The maintenance of the risk level in this area reflects the continuing activity to maintain our contingency arrangements in response to the Covid pandemic and the smoothness of our adjustment to this changed context. We have also made good progress with the development programme, including planning for the developments required as part of the UK 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 generally positive results of the stakeholder evaluation commissioned in quarter 4 of 2019/20 was reported to the July Board meeting and has provided helpful insight into opportunities to strengthen and include in our development plans for this year. SMT believe this risk is stable in September 2020. |
| **4 - Failure to utilise our capabilities effectively** *(Delivery a-e) (Development a-d) (Deployment a, c and d)* | → | ↑ **16** | → **16** | → **16** | Recruitment was put on hold in quarter 1. SMT considered the five vacancies we had when headcount in July and agreed to focus recruitment on building our capabilities to achieve our development programme objectives for the remainder of this year. We have started to recruit to a range of contract positions to meet these needs and have appointed a temporary Change Manager who took up post in mid-August, and have gone out to recruitment for a Data and Intelligence Lead. We have also approved recruitment to fill a temporary Regulation Officer vacancy to address workload pressures. Workload and pressure on staff continues to be monitored closely by the management team and improvements in management information introduced during Quarter 1 have been helpful in supporting this approach and embedding better use of data and management information throughout the business.

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. The sequencing of this work will need to take into account interdependencies across the development programme.

As of September, the HTA continues to operate in an uncertain environment and is now assessing how best to adapt and move to a new operating normal. During the initial peak of the pandemic we agreed to plan over a shorter time horizon quarter by quarter. There is now an impetus to plan over a longer horizon. In the light of the competing pressures and the uncertainty, there was a risk of people resource being used ineffectively. SMT believe the planning and monitoring activity undertaken from July has stabilised this risk. SMT believe this risk is stable in September 2020. |
| **5 - Insufficient, or ineffective management of, financial resources** *(Deployment b)* | → | → **8** | → **8** | → **8** | 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 confirmation is still awaited.

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. In addition to the potential issue in obtaining payment from establishments who may be suffering reduced income or cash flow issues themselves as a result of the pandemic, we are also conscious that there may be a risk that some establishments challenge payment of license fees if they develop a perception that the lack of site visits by the HTA means they are not obtaining value for money for their fees. SMT believe this risk can be managed through continuing proactive communication with our sectors to demonstrate the range of continuing regulatory activity still being undertaken. SMT believe this risk is stable in September 2020. |
| **6 - Failure to achieve the benefits of the HTA Development Programme** *(Development objectives a-d)* | → | → **9** | → **9** | → **9** | The removal of costs associated with site visit inspection along with the pause in recruitment has provided some headroom for development investment within the existing budget. The scoping of what could be achieved to fulfil the HTA's strategy has progressed well and at present the risk is stable.

The office move project is underway and progressing well, and is being managed by the HTA's permanent project manager (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 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. SMT believe this risk is stable in September 2020. |

Risks are assessed by using the grid below

Risk scoring matrix

		1. Rare (≤10%)	2. Unlikely (11%-33%)	3. Possible (34%-67%)	4. Likely (68%-89%)	5. Almost Certain (≥90%)
Impact	5. Very high	5 Medium	10 Medium	15 High	20 Very High	25 Very High
	4. High	4 Low	8 Medium	12 High	16 High	20 Very High
	3. Medium	3 Low	6 Medium	9 Medium	12 High	15 High
	2. Low	2 Very Low	4 Low	6 Medium	8 Medium	10 Medium
	1. Very Low	1 Very Low	2 Very Low	3 Very Low	4 Low	5 Medium
Risk Score = Impact x Likelihood				**Likelihood**		

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

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	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
1	**Failure to regulate in a manner that maintains public safety and confidence and is appropriate** **(Risk to Delivery objectives a-d & f Development objectives a-d)** *Risk Owner:* **Allan Marriott-Smith**	*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 a virtual regualtory 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 pilot virtual regulatory assessment in the HA sector commenced in quarter three 2020/21.
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory Report made in July 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.
						The HTA has produced a detailed business plan for the remainder of the year. These plans are approved by SMT and balance core regulatory functions, development priorities and resource deployment considerations.				X	X		Preventative	Business plan for 2020/21 has been produced and approved for publication by the sponsor Department.	Quarterly reporting to Authority and DHSC in May 2020 reflected progress against 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 Board quarterly.	Quarterly report made at July 2020 Authority meeting. Mid-year PDP reviews due to be completed by 2 October 2020.
						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	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 I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL I	RESIDUAL L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
2	**Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:** • **relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)** • **caused by deficiency in the HTA's regulation or operation** • **where we need to regulate, such as with emergency mortuaries** • **that causes business continuity issues** **(Risk to all Delivery Development and Deployment objectives)** Risk owner: **Nicky Harrison**	_**Cause**_ • _Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)_ • _Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)_ • _Failure to work effectively with partners/other organisations_ • _Breach of data security_ • _IT failure or attack incident affecting access to HTA office_ • _External factors such as terrorist incident, large scale infrastructure failure or pandemic_ _**Effect**_ • _Loss of public confidence_ • _Reputational damage_ • _Legal action against the HTA_ • _Intervention by sponsor_	5	3	Future, should event occur	Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff	3	2		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 quarterly Board reporting as they arise and as relevant.
						Availability of legal advice				X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place
						Fit for purpose Police Referrals Policy				X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Police referral process used regularly by SMT and captured in SMT minutes.
						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 at November Board meeting.
						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 quarterly reporting to the Board. 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	LOD 1	LOD 2	LOD 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**	*Cause*	5	4	Ongoing	Log of issues known to the HTA with respect to the legislation to inform DH and manage messages	4	3		1	2	3		*Ongoing log*	*Log in place and stable.*
		External factors									X		Monitoring		
	(Risk to Delivery objective e, and Development c)	• *No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)*				Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope			*Outcome of internal audit on the adequacy of these arrangements is anticipated in October with advice on improvements*	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*
	Risk Owner: **Louise Dineley**	• *Rapidly advancing life sciences*				Active management of issues raised by the media – including the development of the HTA position on issues					X		Preventative/ Detective	*Quarterly reports to Board on communication (including media) activities*	*Last report July 2020*
		• *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates*				Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence					X		Monitoring	*Quarterly Accountability meetings with DH*	*Last assured position from DHSC on 31 July 2020*
		• *Introduction of deemed consent for Organ donation in England*				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.*
		• *Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario*													
		Matters which certain stakeholder groups believe require review				Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge				X			Preventative	*Duty and its uses understood by SMT and Chair*	*Advice and guidance continues to be provided, for example on the Private Members Bill - Organ Tourism and Cadavers on Display, 2020.*
		• *Scope of relevant material e.g. waste products*													
		• *Licensing requirements e.g. transplantation research*													
		• *Regulation relating to child bone marrow donors*				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.*
		• *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				Extensive Professional Evaluation Survey being undertaken in Q4 2019/20. Report to Board in July 2020.				X			Preventative	*Evidence from Professional Evaluation*	*Evidence from Professional Evaluation presented to the Board in July.*
		• *Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure*				Proactive horizon scanning and development of policy in emerging/complex areas. Further strengthening building on existing system.				X			Preventative	*Horizon scanning improvement is one of the six strands of the development programme*	*Update on this work presented at July Board meeting*
		• *Police holdings*							*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.*	
		• *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*													

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 Head_ • _Loss of productivity as a result of the effects of changes to ways of working_ • _Data holdings poorly managed and under-exploited_ • _Inadequate business technology or training in the technology available_ • _Lack of ring-fenced resource for 'no-deal' EU Exit_ _**Effect**_ • _Poor deployment of staff leading to inefficient working_ • _Disaffected staff_ • _Increased turnover leading to loss of staff_ • _Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed_ • _Poor use of technology resulting in inefficient ways of working_ • _Inadequate balance between serving Delivery and Development objectives_	4	4		**People capability**	4	4								
						People Strategy for the period 2019 to 2021 is in effect				X	X		_Preventative/ Monitoring_	_Authority approval of the Strategy_	_Authority approved the Strategy at its meeting in February 2019 and is provided with regular updates on all facets of its progress in quarterly board reporting. Most recently in July 2020._
						Full suite of people policies and procedures (including performance management)				X			_Preventative/ Monitoring_	_Full suite of policies in place and available on Wave_	_https://intranet.hta.gov.uk/pages/polici es_forms_
						External assessment of utilisation of capabilities						X	_Monitoring/ Detective_	_Internal audit 'Utilisation of capability' provided moderate assurance in July 2019_	_ARAC received the audit report and monitors progress against recommendations - most recently June 2020_
						Adherence to the HTA Workforce Capability Development Framework				X			_Preventative_	_SMT approved the Framework in September 2020 - as a response to internal audit recommendations_	_ARAC to receive update on the Framework at its meeting in October 2020_
						Investment in the development of the HTA leadership team				X			_Preventative_	_External consultants engaged to assess team and individual development needs and design appropriate interventions_	_Interventions have commenced including full leadership team workshop in September 2020_
						Handover process is formalised via a checklist to ensure corporate knowledge is retained				X			_Preventative/ Monitoring_	_Handover checklist is in place and in operation._	
									More formal assessment of future capability needs and how these should be met including through better knowledge of internal skills	X	X		_Preventative/ Monitoring_	_Director and Head of HR assessing capability needs as part of future operating model_ _HTA Workforce Capability Development Framework sets out how capability needs will be met_ _Head of HR has implemented a register of skills within the HTA_	_SMT will be agreeing its approach to filling specific immediate capability needs in October_ _Development Programme is picking up medium to long term capability needs._
									Establish a formal role within SMT terms of reference to look holistically at people and capability issues across the organisation focussing on short and long term impacts and deliverables.		X		_Preventative/ Monitoring_	_SMT terms of reference and SMT minutes_	_SMT ToRs review is in process supported by external advisers. Due to be in place by end October 2020_
						Data capability									
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)				X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019
						Appropriate procedures to manage personal data including GDPR compliance.				X		X	Preventative/ Monitoring	Internal audit on GDPR compliance provided moderate assurance.	Internal audit report in March 2019. Part of ongoing Cyber and data security and SIRO reporting.
						Business technology capability									
						Staff training in key business systems				X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems. New remote induction programme was launched in Summer 2020.
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date				X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2020
						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 version in August 2020. (Being reviewed by SMT)
						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 July 2020
						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 overall environment is more uncertain than normal.
						Reserves policy and levels reserves				X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2019
						Delegation letters set out responsibilities				X	X		Preventative	Delegation letters issued annually	Issued in May 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 2020 - 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 July 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 lnote 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	*Change Manager appointed in August 2020 to support the development of capacity & capability across the organisation*	X			Preventative	Recruitment of an HTA Programme Director	The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.
						HTA approach to the management of change projects *(underpinned by project management methodologies)*				X			Preventative	Dedicated permanent project manager appointed	PM in place an operating effectively
						A number of trained project managers among HTA staff			*Project Management skills further strengthened by introduction of a toolkit and induction session by PM*	X			Preventative		
						Experience of procurement and contract management				X			Preventative		
						Existing mechanisms for engaging staff			*Plans developing for strengthening internal communciations function*	X			Preventative		
						Well established corporate governance arrangements and financial controls					X		Monitoring	*Internal audit of key controls*	Assurance provided by Internal Audit of adequacy of key financial controls
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding			*Further alignment of projects on the business plan in Q3 & Q4 to strengthen phasing of actions, resource deployment and consolidation of actions to encourage smarter working.*	X			Preventative	*Progamme plan in place*	Update reported to July Board meeting
									Embed Benefits Realisation Management methodology within programme	X			Preventative		
									Introduce a Programme Management Office	X			Preventative		New PM appointed, procedures and PMO to be established by - date TBC
									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	*Date TBC*
									Training plan to encompass project and change management and HTA approach	X			Preventative		*Date TBC*
						Strengthened planning supports a single message and focus on an agreed set of priorities			Development of procurement plan to deliver the DDAT Strategy	X			Preventative		*Plan in place, 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		*Date TBC*
						Project management includes a monitoring of costs			Schedule a regular programme of staff engagement events	X			Preventative		*Date TBC*
						Scope of projects aims to deliver benefits including on a phased and incemental design			Establish an external stakeholder communications and engagement plan	X			Preventative		
									Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		*To be actioned at next recruitment round*
						Agreed priorities in Business Plan and underpinning foundations for future strategy maintain required pace			Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
									Appointment of external critical friend to counter potential optimism bias			X	Preventative		

Board Supplementary Data Annex document
Quarter 2 2020/2021

|			
Date	5 November 2020	**Paper Reference**	HTA (23b/20)
Agenda Item	6	**Author**	Nicolette Harrison
Protective Marking	OFFICIAL	**Author Contact** Nicolette.Harrison@hta.gov.uk	

Purpose of Report

1. This report sets out a high-level overview of activity in quarter two 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
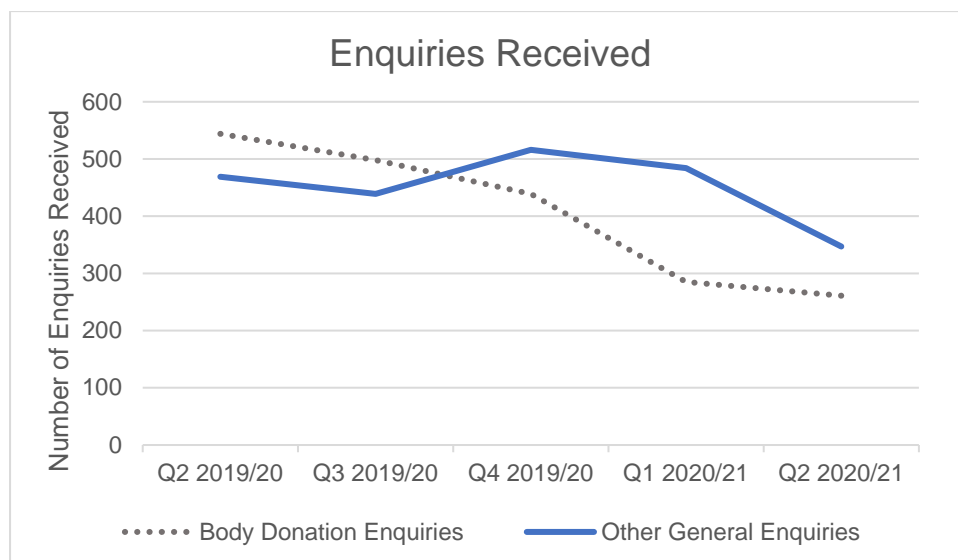
3. Table 1 displays the number of general enquiries received for each sector (excluding body donation enquiries).

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

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

Human Application	62	78	103	100	86	282	316
Organ Donation and Transplantation	11	8	6	12	14	30	38
Post Mortem	85	88	147	196	116	178	379
Public Display	5	5	8	1	6	21	22
Research	68	75	53	74	62	139	248
Removal	2	1	0	6	1	1	4
No Sector Assigned	194	141	178	75	43	908	679
Total	469	439	516	484	347	1,719	1,822

Licensing

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

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

Sector	New Licence Application	Licence Applications with Decision Made	Satellite Additions	Revocations	Satellite Revocations
Anatomy	1	0	0	0	0
Human Application	3	0	2	0	3
Organ Donation and Transplantation	0	0	0	0	0
Post Mortem	0	2	1	0	1
Public Display	0	0	0	0	0
Research	2	0	2	4	3
Total	6	2	5	4	7

5. Six new licence applications were received in quarter two 2020/21 (three applications were received in the Human Application sector, two of which were the first EU Exit applications. Two applications were also received in the Research sector and one application was received in the Anatomy sector).

6. In quarter two 2020/21, decisions were made on two applications. Both were emergency mortuary licence applications in the Post Mortem sector, one of which was the first licence for a funeral director organisation.

7. There were two satellite additions in the Human Application sector, one in the Post Mortem sector and two in the Research sector.

8. A total of four revocations took place in the Research sector.

9. There was a total of seven satellite revocations in quarter two (three were in the Human Application sector, one in the Post Mortem sector and three in the Research 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
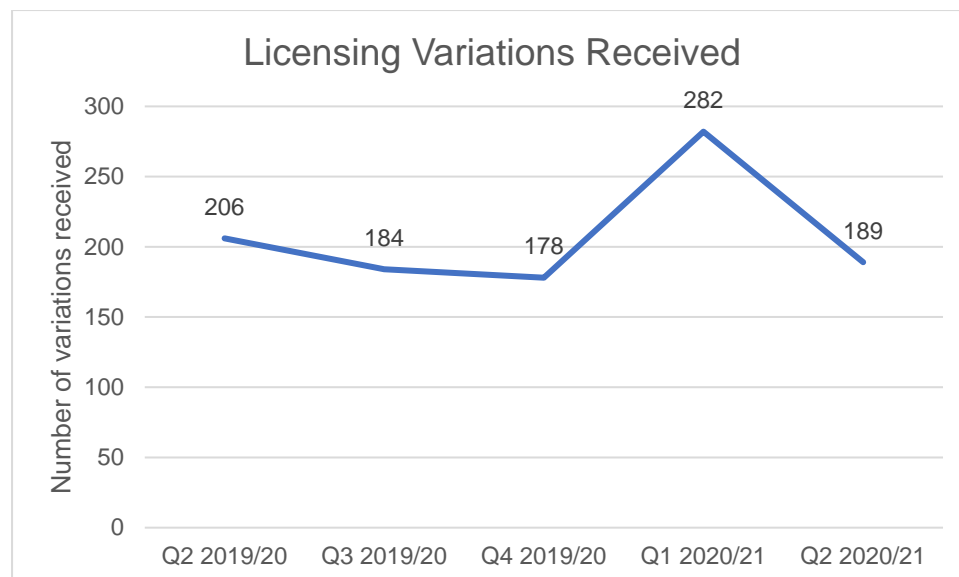
Table 3: Licensing variations received by sector

Sector	Q2 2019/20	Q3 2019/20	Q4 2019/20	Q1 2020/21	Q2 2020/21	2018/19 Total	2019/20 Total
Anatomy	8	10	8	6	3	25	30
Human Application	72	54	83	127	102	260	118
Organ Donation and Transplantation	7	12	4	6	4	27	27
Post Mortem	72	55	40	89	39	158	205
Public Display	5	9	1	5	2	9	16
Research	42	42	42	49	39	155	165
Removal	0	2	0	0	0	0	2
Total	206	184	178	282	189	634	708

12. A total of 189 licensing variations were received in quarter two. The number received has returned to the average number received before the COVID-19 period.

Living Donation

13. Figure 3 shows the total number of living donation cases approved by the Living Donation Assessment Team (LDAT) and panel.

14. In quarter two, 122 cases were approved by the LDAT and 18 cases were approved by a 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

Living Donation Cases Approved
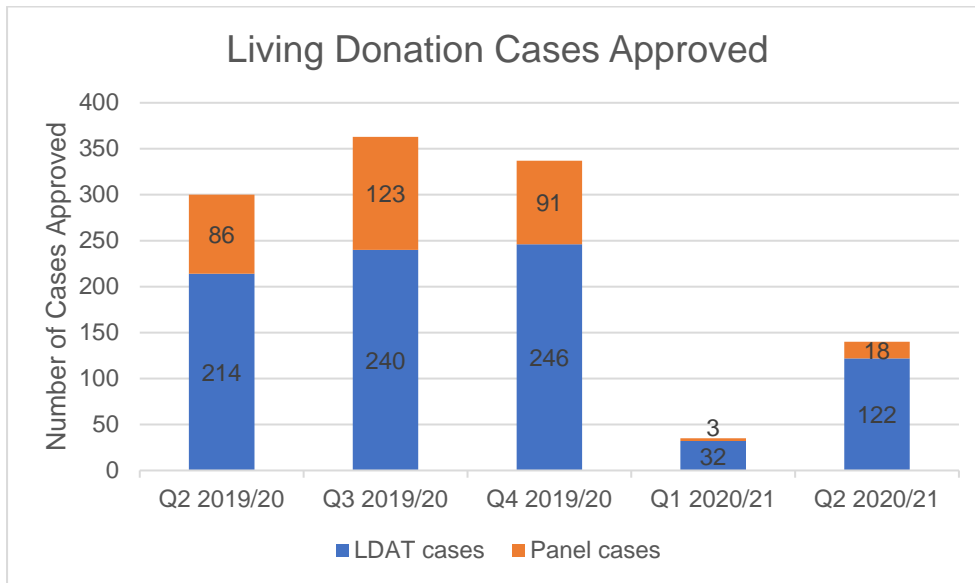
15. Table 4 below shows the total number of bone marrow and peripheral blood stem cell (PBSC) cases approved in quarter two compared to preceding quarters.

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

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

Incidents – HTARIs

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

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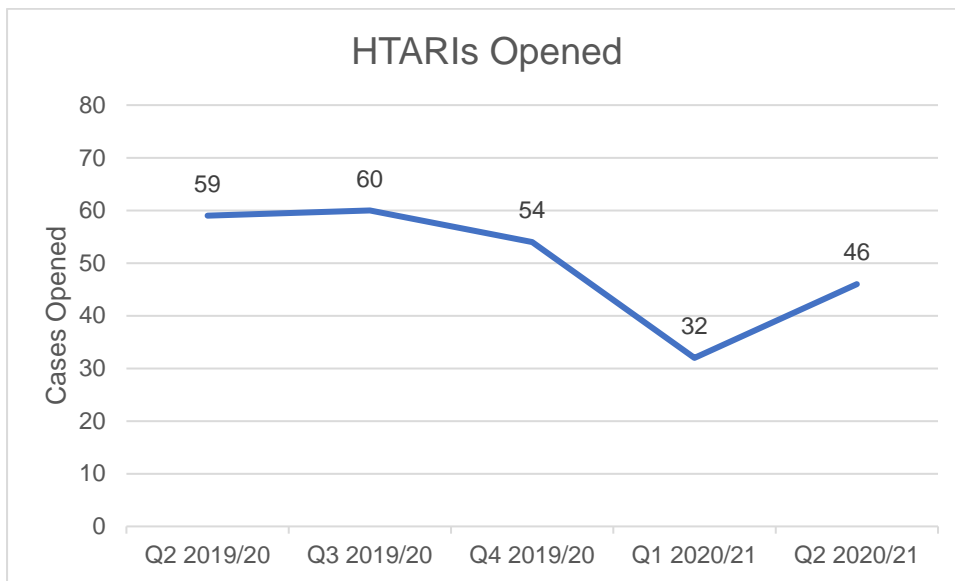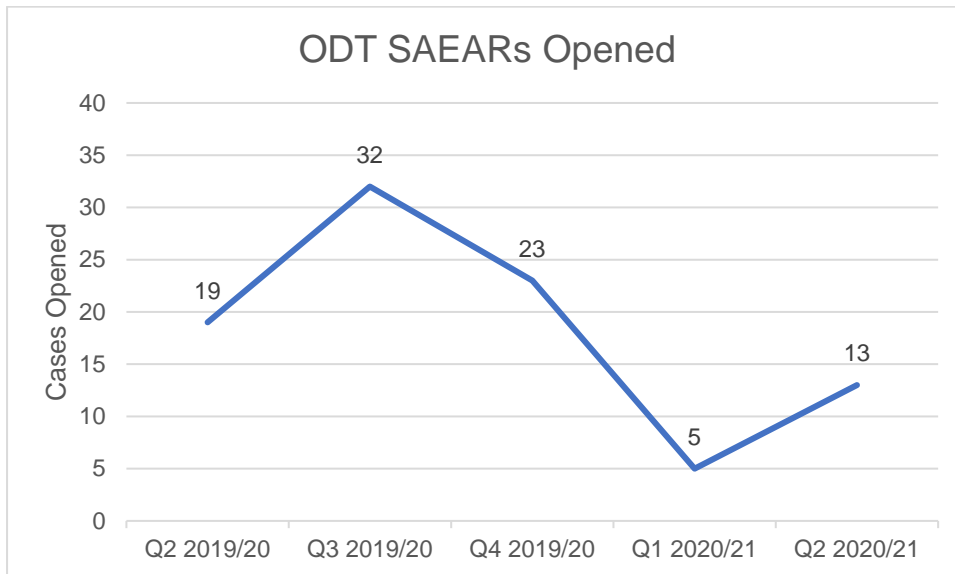

17. Figure 5 displays the number of HTARIs resolved in quarter two compared to the preceding quarters.

Figure 5: HTARI cases resolved during quarter in the Post Mortem sector
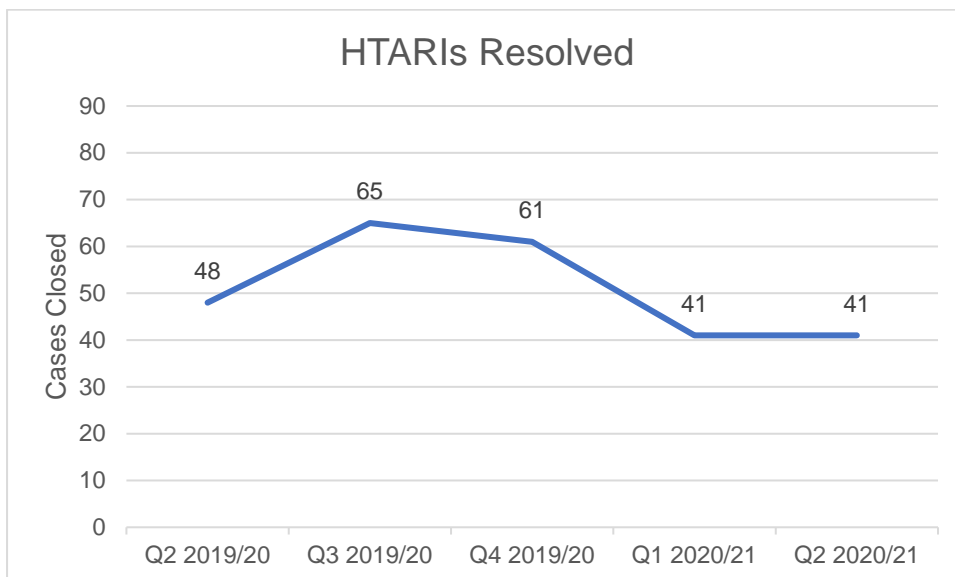
Incidents – HA SAEARs

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

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

HA SAEARs Opened
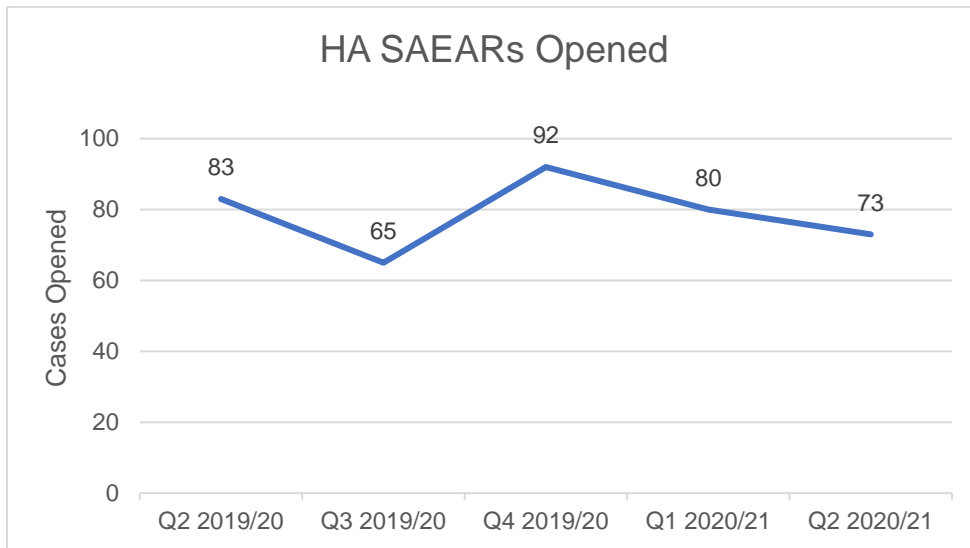
19. Figure 7 displays the number of HA SAEARs resolved in quarter two compared to preceding quarters.

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

HA SAEARs Resolved
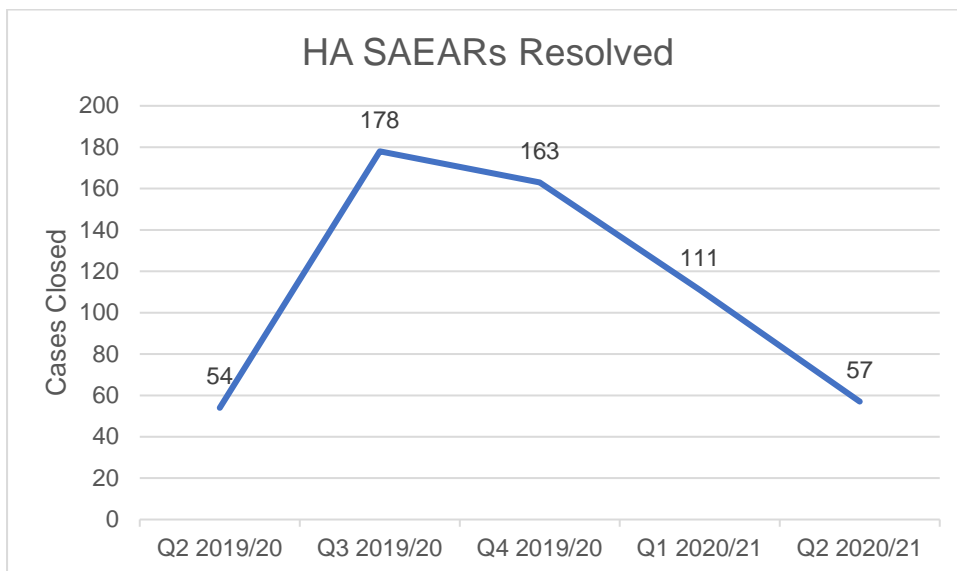
Incidents – ODT SAEARs

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

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

ODT SAEARs Opened

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

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

ODT SAEARs Resolved
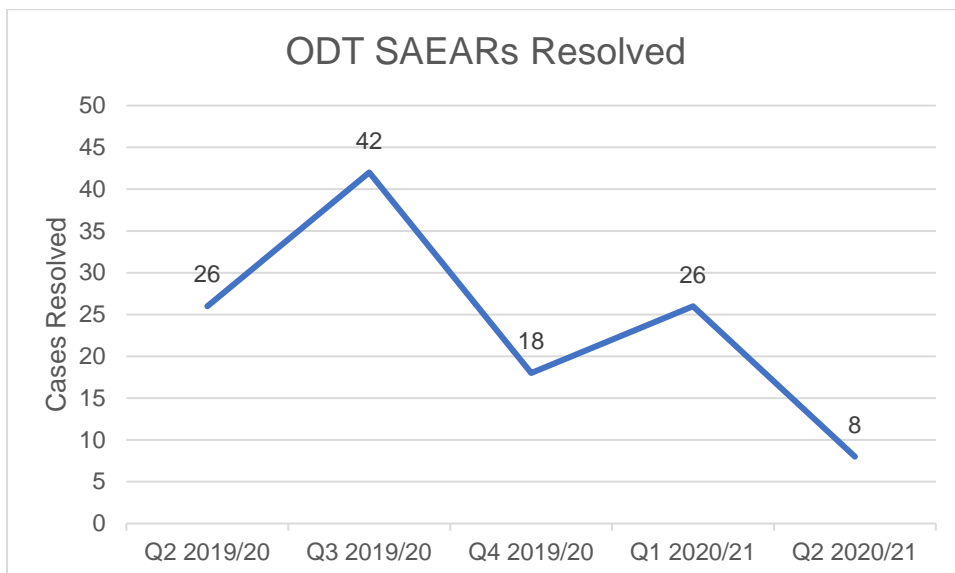
CAPA Plans

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

23. A total of eight CAPA plans were opened in quarter two. Seven CAPA plans were opened in the Post Mortem sector and one was opened in the Human Application sector.

24. A total of 28 CAPA plans were closed in quarter two. Eleven CAPA plans were closed in the Human Application sector, eleven were closed in the Post Mortem sector, four closed in the Research sector, one closed in the Anatomy sector and one closed in the Public Display sector.

Figure 10: Number of CAPA Plans opened and closed during quarter
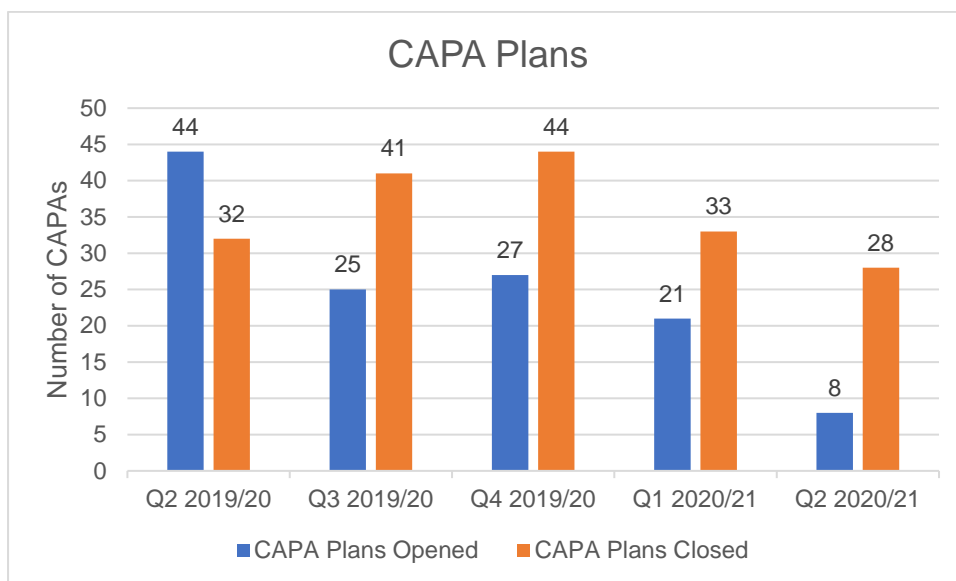
25. Table 5 shows all open CAPA plans at the end of quarter two and the length of time they have been open.

26. There were a total of 37 open CAPA plans at the end of quarter two. Eight CAPA plans have been open for less than six months, twelve have been open between 6-12 months and 17 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	3	5	0	0	0	**8**
6-12 months	0	5	7	0	0	0	**12**
> 12 months	0	2	14	1	0	0	**17**
Total	0	10	26	1	0	0	**37**

Website Analytics

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

Table 6: Audience Size

	2020/21	2019/20
Visits	45,176	55,457
Sessions	62,461	77,568

28. Overall traffic is down roughly 20% compared to the same period last year. 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 32s	2min 46s
Bounce rate	41.32%	39.27%

29. Engagement statistics both fell by a fairly moderate amount. 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. This section reveals what may be the root cause of the drop off in traffic to the website. In general, content aimed at a public audience, particularly in relation to body donation, is down as a proportion of page views. This suggests that though professionals are still using our website in similar numbers to the previous year, there has been a significant drop off in members of the public seeking guidance on our website, specifically in regard to body donation.

Additional notes

31. There was a significant spike in website traffic on Wednesday 7 August 2019, which is largely anomalous. As such this skews the statistics somewhat.

Conclusion

32. There is little to mark this period as especially significant, though the fall in traffic is something that we will continue to monitor into the next quarter.

Comparison graph (users over time)

Board paper

Date	5 November 2020	**Paper reference**	HTA (24/20)
Agenda item	7	**Author**	Louise Dineley, Director of Data, Technology and Development

Protective Marking	OFFICIAL

HTA Development Programme

Purpose of paper

1. This paper aims to provide an update on the HTA's Development Programme and to set out the scope of work for the next six months.

Decision-making to date

2. The priorities in the Development Programme continue to reflect and drive forward core themes of the HTA's Strategy.

3. The CEO approved this paper for release on 27 October 2020.

Action required

4. The Board is asked to note the paper.

Background

5. For the last three years the HTA Strategy has been committed to strengthening the use of data and developing our technology to support the delivery of effective regulation. Progress in the achievement and realisation of the intended benefits had been constrained due to the availability of resources (financial and people). In quarter four 2019/20 there was a renewed drive to realise these strategic objectives through successful cloud migration, implementation of Microsoft 365 and the establishment of a baseline on our current and future data, intelligence and information requirements.

6.   The coronavirus pandemic presented an opportunity to reset our plans and use of resources.   In quarters one and two, activity levels across the business have been generally lower than in previous years.   This offered the opportunity to focus on progressing developments previously constrained by resources through targeted investment.

7.   At the July Board meeting we shared an update on the Development Programme confirming the six priority projects and their scope. Since then the focus has been on detailed project planning – including bringing outstanding actions, recommendations and long-standing issues into scope. Planning also requires the resolution of issues of policy, development of capabilities and the strengthening of internal systems and processes. This alignment of actions will help in future proofing some of the proposed developments and establishing a sustainable HTA Target Operating Model for the next three-year strategy.

Update on the Priority Projects

8.   In quarter two, the projects have focussed on scoping, planning and preparing for implementation: More specifically this has included:

     a.   Project planning
     b.   Mapping interdependencies
     c.   Identifying benefits
     d.   Management of resources

9.   We have also mapped a critical path for each project for the remainder of this financial year alongside business as usual and other operational developments. In addition to setting out what will be achieved this year, this will provide the foundations to support the HTA Strategy 2021-24. Further work will be undertaken to extend these plans into 2021/22.

10.   ***Strengthening the use of data and intelligence*:** After commissioning Transforming Systems in August, further progress has been made in the development of how the HTA uses data and intelligence in the delivery of effective regulation. The commission includes support to draft a Data and Intelligence Strategy and the identification of a core data set based on existing data collection. This data set will then be used to develop a proof of concept model that utilises existing systems and data sources to help identify potential areas of risk and better target the HTA's regulatory response. Early demonstration of a proof of concept has been positively received and will be fully evaluated in the coming weeks. This proof of concept demonstrates what could be achieved in terms of technical capabilities and current data sources. A key factor in any further development of our intelligence and insight capabilities will be the identification and collection of relevant data and establishing further reliable data sources. A further

commission is anticipated after the evaluation of the proof of concept to further develop the thinking on the end state and strengthened data and intelligence capability across HTA activities.

11. ***Developing the HTA Operating Model****:* The early scoping of the Operating Model has confirmed the core functions and provided a high-level view on proposed changes to past methodologies. In scoping the future purpose of the functions, licensing, data, assessment (previously inspection), corrective action and authoritative voice, there are a number of changes to our systems, processes and people that will be needed. A critical interdependency to the development of a future Operating Model is the development of data and how this is used as part of an updated regulatory offering and in the assessment of compliance in licensed establishments. A key change from the current regulatory approach will be the use of a range of assessment tools. Site visits will continue to be an option and will be supplemented by ongoing insight assessments and targeted virtual regulatory assessments.   As work progresses in quarters three and four our aim will be to test the proposed changes internally and engage the views of external stakeholders.

12. ***Implementing an Electronic Document Record Management System (EDRMS):*** The planning for the EDRMS project has built on the requirements gathered in quarter four 2019/20 and outstanding other actions - including past internal audit recommendations. In preparation for the implementation of the EDRMS solution a number of key actions need to be completed. One of these has been establishing a state of readiness for document migration from IMPACT.   In parallel to these housekeeping arrangements, the identification of a preferred solution options has continued.   To support this decision and aligned to the project to optimise Microsoft 365 functionality, there has been a strategic focus on the HTA's future IT requirements. The draft IT strategy provides a framework and a set of principles for future investment and development that ensures interoperability of our systems as well as phased developments against a central vision. This is particularly relevant to the scoping of the EDRMS project with phase one focused on the replacement of IMPACT and subsequent phases considering the future use of CRM, other systems and the flow and exchange of data.

13. ***Optimising Microsoft 365 functionality****:* The adoption of Microsoft 365 at the end of quarter four provided the HTA with a wealth of functionality. The added functionality of Teams as a collaboration and communication tool has been a significant factor in the successful transition to remote working in the last six months. Looking forward, there is an appetite to build on the strong early uptake and utilise more of the functionality offered through Microsoft 365 to support collaboration in the development projects and as part of business as usual. The project actions focus on embedding of Microsoft 365 and the tools available.   Examples include the development of a series of guides, the identification of internal champions and "super users" to encourage adoption across

peer groups and the use of personal activity data to identify additional apps to individual users.

14. ***Horizon Scanning & future regulation***: The insight from internal horizon scanning has acted as a key source of insight to the development programme design to date and towards the early thinking for the HTA Strategy 2021-24. There are a number of areas currently being explored, including:

- Approval of living donation cases
- Consent provisions for imported material
- Adaptive licensing models
- Information sharing and partnership working including innovative ways of working, to support better regulation initiatives, burden reduction and busting bureaucracy.

15. ***Organisational Preparedness***: The emerging developments and details from each of the projects share a common theme of change. The developments identify changes to what we do, how we do it and the additional skills and expertise required for delivery. In August we successfully appointed an experienced Change Manager to help and prepare the organisation for the scale of change anticipated over the next six months. This change is not limited to the Development Programme and encompasses the move of the office to 2 Redman Place and the extension of remote working as part of an ongoing response to COVID-19 and with existing planned changes to employment contracts. In the first six weeks of appointment the Change Manager has made good progress in setting a foundation with staff for the changes ahead. Actions include the introduction of a change management framework and change impact assessments for priority projects, and the start of a series of internal change management sessions.

Next steps

16. Over quarter three there are a number of planned deliverables. These include:

- Completion of an initial proof of concept on the data and intelligence model and commissioning of next steps including the commission of external data collection testing.
- Agreement of the recommended EDRMS solution and implementation with aim for completion in early January.
- High level design for the future Target Operating Model including a detailed profile of core functions (licensing, data and assessments)
- Completion of change impact assessments for all projects
- Implementation of external engagement strategy of stakeholders in proposed changes to the regulatory model

Board paper

Date	5 November 2020	**Paper reference**	HTA (25/20)
Agenda item	9	**Author**	Sumrah Chohan, Transplant Manager
			Jennifer Cole, Transplant Officer
			Laura Mullally, Transplant Officer

Protective Marking	OFFICIAL

Living Donation Panel Case Recommendation

Purpose of paper

1. The purpose of this paper is to update Members on the outcome of the recent trial of the proposed recommendation process for cases requiring decision by a panel.

Decision-making to date

2. This paper was approved by the CEO on 27 October 2020.

Action required

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

Background

4. In July, Members were provided with a proposal for a new way of assessing cases requiring panel decision. This was with the aim of reducing the time dedicated to panel cases to allow more time to be put to wider governance and oversight activity. The Board agreed to trial the new process for a period of eight weeks. The trial started on 3 August and ended on 30 September.

5. During the trial, Members were asked to base their decision on the recommendation template completed by a member of the Executive. The recommendation template was designed to summarise the key information required by law to make a decision. Although Members were still able to access the Independent Assessor (IA) report,

referral letter and donor declaration, Members were encouraged to review the recommendation only and base their decision on the information within it.

Trial

6. To ensure all Members were given sufficient opportunity to participate in the trial, Members were assigned a minimum of two panel cases. A total of 29 cases were reviewed during the trial, with an average of seven cases completed per Member.

7. Due to COVID-19 and the cancellation of the National Kidney Sharing Scheme matching run in April, there was a substantial decrease in the number of cases requiring panel consideration. Therefore, in the weeks where there were no cases requiring panel consideration, Members were asked to review substitute (past) cases. To ensure a fair trial, Members who had made a decision on those cases previously were not included. A total of six substitute cases were assigned, in addition to the 23 cases requiring decision.

8. The table below shows the breakdown of the category of cases considered by Members during the trial:

Donation category	Number of cases reviewed by Members
Non-Directed Altruistic Donation	11
Pooled Donation	12
Paired Donation	6

9. Throughout the trial, each completed template has been quality assured by another member of the Executive prior to the case being assigned to panel. The Head of Regulation has also conducted a quality check on a sample of those cases.

Feedback

10. Throughout the trial, all feedback provided by Members was captured. A number of changes were made to the recommendation template as a result. Annex A includes a summary of the feedback relating to proposed changes to the recommendation template and Annex B is the revised recommendation template based on feedback.

11. Whilst all the feedback received was very useful, the Executive has been careful to avoid recreating the detail of the IA report within the template itself.

12. Some Members expressed a preference to read the supporting documents, because of the additional detail provided. However, due to Members' limited time available for HTA business this is not considered necessary in the context of the relative regulatory risks.

13. Alongside feedback collated during the trial, a survey was conducted once the trial had ended to capture an overall sense of how effective the new process had been. In total seven Members completed the survey.

14. Overall, Members felt that the recommendation had been easy, convenient and more accessible to use. The general consensus was that being provided with the template reduced the length of time required to review cases.

15. 86% of those responding agreed or strongly agreed that the recommendation template included sufficient details for them to fulfil the regulatory requirements needed to make a decision. The average time taken to make a decision on the case based on reviewing the recommendation template was ten minutes. This is approximately a 50% reduction in the time spent each reviewing case.

16. When asked whether the HTA should proceed with implementing the new process, 86% of those responding were in favour. Members highlighted that the process is more streamlined and straightforward. It was also recognised that that the Executive regularly provides decisions on cases that do not require panel consideration and are well equipped to provide a recommendation.

17. The additional work for the Executive was highlighted. To mitigate this, the template mirrors the flow of the IA report and includes pre-filled text options where appropriate.

18. In March, the Executive had obtained legal advice which confirmed that Members can appoint a competent person(s) to advise them and provide recommendations, so long as the ultimate decision is made by the panel. To ensure the recommendation template met the requirements, further legal advice has recently been sought on the template itself.

19. This advice has confirmed that the recommendation template provides sufficient information on which a panel can base a decision, provided that the 'yes/no' confirmation boxes are supplemented with detailed supporting information. This is to ensure that each case is considered on an individual basis, which avoids the perception of the new process being a 'rubber stamping' exercise. The advice also suggested some small inclusions to the template for transparency to assure the Board of the considerations made by the Executive when assessing the case and completing the recommendation. The advice also suggested we include a "maybe" option for any cases for which it is considered too difficult to provide a recommendation and it is preferred that the panel make their own assessment. Further detail on the tracked changes made to the template can be found in Annex B .

20. At the July meeting, Members also discussed whether the timeframe for consideration of cases could be reduced from ten to five working days. It was agreed at that point to

be left as ten working days. However, the Executive was asked to keep this under review to understand if five working days was realistic in practice.

21. This is a change that would be welcomed by stakeholders and the sector. NHS Blood and Transplant's new draft ten-year strategy includes the commitment to developing the existing kidney sharing scheme in order to continue to maximise transplant opportunities. On this basis, it would safe to assume that we will continue to see an increase in the number of cases requiring panel decision and decisions being needed more quickly by transplant centres.

22. In addition to 86% of survey respondents noting the time taken to assess a case had decreased by 50%, in 2019/20 71% of cases were resolved within five working days demonstrating that this target is achievable.

23. As set out in the July paper, a separate process will continue for those cases where the decision making has been retained by Members. This may be because these cases are more challenging, complex or novel to assess and ensures we continue to focus additional scrutiny where it is most needed. This would include cases where the Executive is minded not to approve, cases where there is an element of economic dependence, novel donations and directed altruistic where the donor is an overseas donor. These would remain at ten working days.

Next steps

24. The Executive's recommendation is that the new process is adopted on a permanent basis and the timescale for consideration of cases is reduced from ten to five working days.

Annex A

Summary of feedback proposed to improve the recommendation template

Feedback	Comments	Outcome
Some Members expressed a preference to read supporting documents, expressing they would miss the detail it provided.	Members are reminded that their decision should be based on the recommendation template, to reduce time taken by Members to assess cases. This would allow for greater strategic focus by the Board across the whole of the HTA's regulatory remit.	Supporting documents and IA report remain available to all Members.
Concerns with the recommendation template being in Word format, leaning to possibility for alterations to be made.	The team agreed and recognised this a was necessary change.	All recommendation templates are now saved as a PDF.
It was suggested that a section be included to highlight to the person reviewing the template whether the donation was taking place in Scotland or not as additional checks are needed if this is the case.	Although the template format of the recommendation has reminders for the team using it to complete additional sections if the case is based in Scotland, the team agreed it would be helpful for this to be highlighted to panel members early on in the template.	A tick box was added to the document to indicate whether the donation was taking place in Scotland.
Rather than include confirmation that the risks surrounding COVID-19 had been discussed in the 'understanding risks' part of the recommendation, it was proposed a separate area be included so that it was not missed.	Given the current circumstances surrounding COVID-19, it was agreed that it would be easier for Members to be assured of the donors understanding of these risks if they were separate from the general risks.	The template was amended to include confirmation of the donor's understanding.

Each recommendation should be dated and include the job title of the individual completing the template.	Team agreed date should be added but decided not to include job titles.	Recommendations now include the date of completion.
The recommendation should include confirmation that prospective donors had been assessed in accordance with the Transplant Guidelines and deemed medically and psychologically suitable to be a living organ donor.	To remain as proportionate as possible, decision made not to include this as clinical teams have responsibility to ensure this happens.	No change made.
It was suggested that the recommendation template was amended to include a statement confirming relevant background documents have been reviewed and that the IA has verified the identity and relationship of the donor and recipient.	The aim of this feedback was to provide reassurance to panel members that these checks have been made. The Executive agreed it was an important change to make.	The statement is included in all recommendations where appropriate.
The recommendation should include a tick box to confirm whether the donor and recipient were seen separately and together.	To remain as proportionate as possible, decision made not to include this.	No change made.

Annex B

Changes to the template as a result of Member feedback

The updated template includes the following additional information following feedback from Members:
- Confirmation that the donor understands COVID-19 related risks;
- Confirmation of whether the transplant will be taking place in Scotland or not;
- The date the template was completed; and
- A statement to confirm the review of supporting documents and the IA report has been completed by a member of the Executive, and that the IA has viewed suitable ID / evidence of relationship

Changes to the template based on legal advice

As per legal advice from Fieldfisher, we have also included guidance in italics for some sections of the recommendation template as a background to what was considered by the Executive when completing the template. A "maybe" option has been added to be used where it is considered too difficult to provide a recommendation and that the panel will need to review the case in its entirety.

Date:

This recommendation template has been completed following review of the referral letter, donor declaration and IA report. I can confirm that suitable ID / evidence of relationship was seen by the IA.

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

Information required by law		Comments
Is this a case where the transplant will take place in Scotland?	Choose an item.	
Category of donation. *Please provide details of both donor and recipient including age, sex/gender, their*	Choose an item.	**Include brief background of the case** i.e. This is a paired/pooled/non-directed altruistic kidney/liver donation case. The donor is a X year old female/male. The recipient is a X year old female/male. The

relationship, and any relevant medical background		donor is the recipients Father/Mother/Brother/Sister/Husband/Wife. **(delete as appropriate)**
Donor: Any difficulties in communicating with the donor. *Please summarise these difficulties in bullet point format (eg: language; recipient is a child)*	Choose an item.	
Delete as appropriate Recipient: Any difficulties in communicating with the recipient. *Please summarise these difficulties in bullet point format (eg: language; recipient is a child)*	Choose an item.	
Donor: Understanding of the nature of the medical procedure and the risk involved. *To include a brief summary of the information provided by the donor to the IA about the nature of the procedure and the risks involved.*	Choose an item.	The donor shows good understanding of the procedure they are expecting, and risks involved, including risk of death. The donor is aware the procedure will be performed via keyhole surgery.
Donor: Specific risks *Please list any specific risks*	Choose an item.	***Delete as appropriate*** There are no specific risks for the donor There are specific risks to the donor: **List**
Donor: Understanding of Covid-19 related risks	Choose an item.	The donor shows good understanding of the risks associated with Covid-19. He/She understands the need to shield both prior to and after the procedure and the precautions

Delete as appropriate SCOTLAND cases - Donor: Any relevant wider implications arising from the intended donation, including the effect on any children or dependent relatives.	Choose an item.	The donor shows evidence of understanding the wider implications. **E.g.** The donor has x children/dependents and xx will be able to look after them after surgery. They have considered the financial implications and are happy to accept these. – **edit as per IA report.**
Donor: Understands that consent may be withdrawn at any time before the removal of the transplantable material.	Choose an item.	The IA has confirmed that the donor understands that they are able to withdraw consent at any time and does not wish to do so at present.
Delete as appropriate 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.	The donor is aware of how the Kidney Sharing Scheme works and its implications. They are aware that their kidney is going to a recipient they do not know. They are aware that the chain might fail where they might donate but their partner may not receive a kidney if there is no suitable match. – **edit as appropriate**
Delete as appropriate 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 understands that they will not know the identity of the recipient and their kidney might fail or be rejected. The donor understands their donation will be starting the paired/pool chain and the effect on the people involved in this chain should they decide to withdraw consent– **edit as appropriate**
Donor: Any evidence of duress or coercion affecting the decision to give consent.	Choose an item.	There is no evidence of duress or coercion affecting the donor's decision to give consent.

Delete as appropriate Recipient: Any evidence of duress or coercion affecting the decision of the donor to give consent.	Choose an item.	The recipient denied any duress or coercion being placed on the donor to consent to the donation.
Delete as appropriate SCOTLAND cases – Recipient: Any evidence of duress or coercion affecting the decision of recipient to accept the organ.	Choose an item.	The recipient denied any duress or coercion to accept the organ.
Donor: Any evidence of an offer of a reward.	Choose an item.	There is **no evidence/there is evidence** in the report to suggest that a reward has been offered to the donor. The donor denies any form of reward, material or monetary.
Delete as appropriate Recipient: Any evidence of an offer of a reward.	Choose an item.	The recipient denied any offer of reward to the donor.
Delete as appropriate Joint interview: Any evidence of duress, coercion or reward from joint observation and discussion.	Choose an item.	The donor and recipient - **edit as appropriate from IA report.** There is **no evidence/there is evidence** in joint discussion to suggest duress, coercion or reward.
Please state any concerns that are relevant to the decision in this case *Such concerns could include: issues with consent; capacity of the donor to understand the procedure and any risks; issues with*	Choose an item.	

potential coercion or reward, etc		
Approval recommended? _Please include here details of the background to the case, the individuals involved and their relationship, the donor's reasons for donating; the key factors in why you have recommended yes / no_	Choose an item.	This is a straight-forward paired/pooled/non-directed altruistic donation case between (state relationship). The donor wishes to donate (state donor reasons). After carefully reviewing the case I am satisfied the case meets the required criteria for approval as the donor has a clear understanding of procedure and risks, and there is no evidence of duress, coercion or reward. The donor is also aware of the paired/pooled/non-directed altruistic process and understands the implications of the scheme. I recommend this case be approved.

Board paper

Date	5 November 2020	**Paper reference**	HTA (26/20)
Agenda item	10	**Author**	Richard Sydee Director of Resources
Protective Marking	OFFICIAL		

Risk Appetite Statement Update

Purpose of paper

1. To provide the Board with a proposed Risk Appetite Statement for adoption.

Decision-making to date

2. This statement was approved by the CEO on 27 October 2020.

Action required

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

Background

4. Following previous discussions with the Board, and work undertaken by the Executive with Accenture Consulting, the Executive is proposing redrafting the HTA's risk appetite and tolerance levels ahead of a further piece of work to assess and where necessary reshape the HTA's Strategic (and subsequently operational) Risk Register.

5. This new statement describes the Human Tissue Authority's (HTA) attitude to risk and outlines the level of risk the organisation is willing to accept in order to achieve its objectives.

6. A clear risk appetite statement:

- Allows for better understanding of our strategic goals, culture, context and sensitivity to risk;
- Contributes to the embedding of risk culture that supports strategic planning and decision-making processes;
- Facilitates a proactive risk management approach to mitigate risks that impact strategic and operational objectives.

Risk Tolerances

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

Extent of Risk Appetite	Risk Tolerance Level	Risk Management Approach
High Appetite (Seek) The HTA will be eager to innovate and to choose options offering potentially higher rewards (despite greater inherent risk).	High Tolerance	Innovate/explore
Moderate Appetite (Acceptable) The HTA is willing to consider all potential delivery options and choose options providing an acceptable level of reward and value for money	Moderate / Medium Tolerance	Open
Low Appetite (Tolerable) The HTA has a preference for safe delivery options that have a low degree of inherent risk and may only have limited potential for reward	Limited / Low Tolerance	Cautious
Minimal Appetite The HTA has a preference for ultra-safe delivery options that have a low degree of inherent risk and only limited reward potential.	As little as possible	Minimal
No Appetite (Unacceptable) The HTA will avoid the risk and uncertainty – key organisational objective	Zero Tolerance	Avoid

Risk Appetite Statement

8. Risk appetite is the amount of risk an organisation is willing to accept in pursuit of its strategic goals.

9. Following our review of the existing approach to risk we propose that the risk appetite statement considers separately five key areas of risk to which the HTA is exposed, and provides an outline of the HTA's appetite for managing these types of risks. The HTA does not have a single risk appetite, but rather appetites across the range of its activities. We recognise that in pursuit of our strategic priorities and outcomes that we may choose to accept different degrees of risk in different areas of the business.

10. Where we choose to accept an increased level of risk, we will do so, subject always to ensuring that the potential benefits and threats are fully understood before actions are authorised, that there is sufficient capacity, and that sensible and proportionate measures to mitigate risks are established.

11. The Executive will manage strategic risks in a manner that is consistent with this statement. The strategic plan and the business plans within the HTA should also be consistent with this statement.

12. Below are the risk appetite descriptions established for each key activity identified.

Business Area Risk Appetite Levels

Regulation

Risk 1 – Failure to regulate appropriately
Risk 2 – Failure to manage an incident

13. The HTA has **NO** appetite for any activity that disregards the need to obtain consent and any incidents that lead to serious public harm or breach of DPA.

14. There is **LOW** appetite for risks that may result in the HTA providing misleading advice, especially when this advice could lead to an adverse impact on patient safety.

Corporate Governance

15. There is a **LOW** appetite for activity that may result in non-compliance with legislation, statutory obligations and government policies. The HTA has a **ZERO** tolerance for deliberate non-compliance with legal, statutory and policy requirements, except in exceptional circumstances.

Reputational

Risk 3 – Failure to manage expectations of regulation

16. The HTA will explore innovative ways of regulating in line with better regulation principles, and will have a clear view on its regulatory risk and areas of oversight. It will not tolerate (**ZERO**) any action that could cause reputational damage.

Capabilities

Risk 4 - Failure to utilise our capabilities effectively

17. The HTA has a **MODERATE** appetite for change to ensure it has the right resources, capabilities and organisational structure to optimise performance in the future whilst delivering value for money.

Information security and management

18. The HTA has a **LOW** appetite for risk that could lead to information or data security breaches and a **LOW** appetite for system failures that could disrupt normal business. We have **NO** appetite for activities that may increase our exposure to threats on our assets arising from external malicious threats.

19. The HTA has **LOW** appetite for activities that may compromise processes governing the use of information, its management and publication. The HTA has **ZERO** tolerance for the deliberate misuse of its information.

Risk 5 – Finance

20. The HTA has a **LOW** risk appetite in relation to management of its finance. It will not tolerate annual expenditure in excess of income or any form of spend that contravenes HMT guidance.   In addition, The HTA has **ZERO** appetite for any incidence of fraud and fraudulent behaviour.

Next steps

21. The risk appetites as drafted above will indicate the HTA approach to tolerating and managing certain risks, where appetite is moderate or high we will look to tolerate levels of risk and potentially pursue opportunities that may benefit the HTA whilst accepting this may increase our short term risk exposure.

22. The Board are asked to consider the Executive's proposal to adopt new risk appetites and tolerances and agree the definitions.
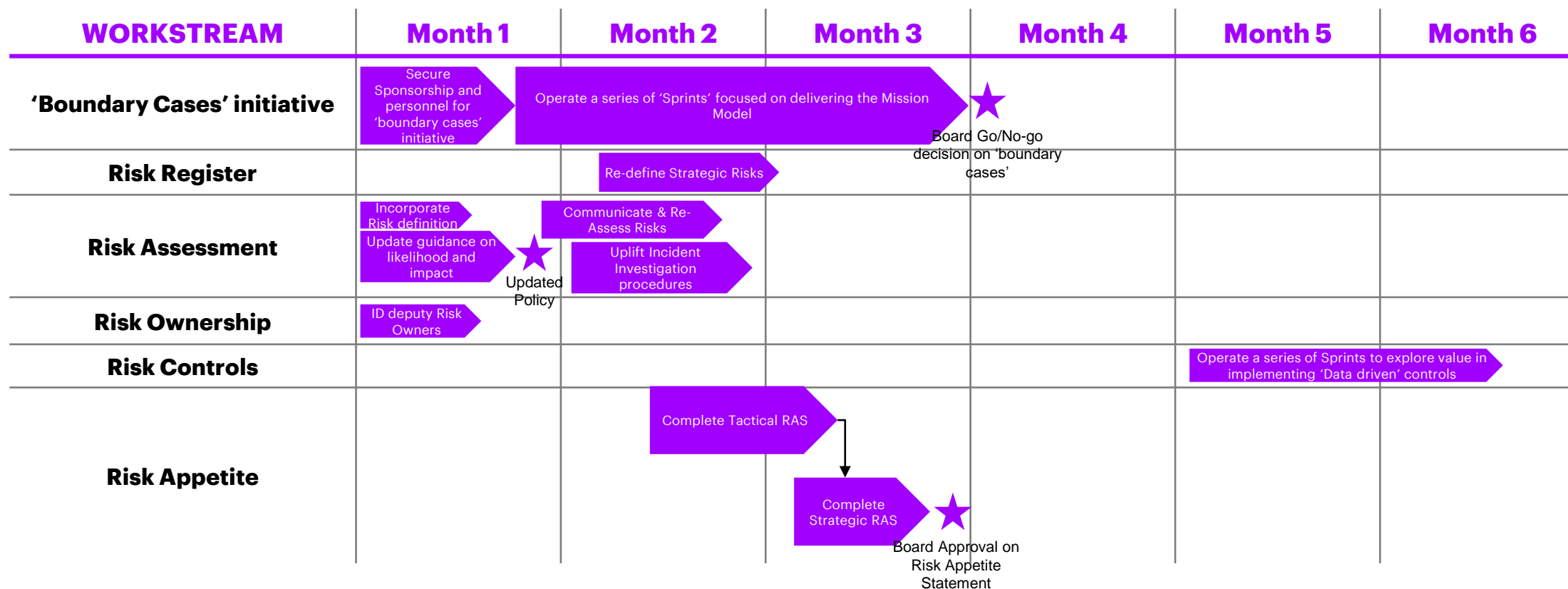
23. Should the Board accept this approach the next steps would be:

- For the Executive and the Board to review the existing Strategic risks and agree whether these are captured and defined appropriately.
- To consider whether our current framing of risk in terms of our strategic objectives, as set out in the current Strategic Risk Register, is still our preferred method or should risks be restated to illustrate internal or external threats/opportunities to the organisation;
- To redraft the strategic risks in light of the decisions above and to state our approach to managing those risks in line with the risk appetites;
- Once the Strategic risk register is redrafted to then turn attention to the operational risk register, ensuring that there is clear synergy between the two and that management of those risks align to our stated risk appetites.

24. The Board may wish to ask ARAC to lead on its behalf, working with the Executive to prepare updates and any revisions to the Strategic Risk Register for the start of the next business year.

Proposed Roadmap

A high-level indicative roadmap for the HTA is provided below

WORKSTREAM	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6
'Boundary Cases' initiative	Secure Sponsorship and personnel for 'boundary cases' initiative	Operate a series of 'Sprints' focused on delivering the Mission Model		★ Board Go/No-go decision on 'boundary cases'		
Risk Register		Re-define Strategic Risks				
Risk Assessment	Incorporate Risk definition / Update guidance on likelihood and impact ★ Updated Policy	Communicate & Re-Assess Risks / Uplift Incident Investigation procedures				
Risk Ownership	ID deputy Risk Owners					
Risk Controls					Operate a series of Sprints to explore value in implementing 'Data driven' controls	
Risk Appetite		Complete Tactical RAS	Complete Strategic RAS ★ Board Approval on Risk Appetite Statement			

N.B: Actual timelines are TBD, depending on the length of time it takes for normal services to resume / COVID-19 measures to be reduced, and the desired 'sequencing' of activities based on HTA priorities.

![HTA Human Tissue Authority logo]

Board paper

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Date	5 November 2020	**Paper reference**	HTA (27/20)
Agenda item	11	**Author**	Richard Sydee Director of Resources
Protective Marking	OFFICIAL		

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Fees proposals for 2021/22

Purpose of paper

1. This paper recommends the budget to be recovered from licensed sectors and the licence fee structure for 2021/22.

Action

2. The Board is asked to agree:

   a) the total HTA budget of £5.3m.
   b) the proposal not to increase fees for 2021/22 and maintain fee recovery at £3.9m.

Decision-making process to date

3. At its meeting on 23 October 2020, SMT agreed to leave fees unchanged for the 2021/22 financial year.

Background

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

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

Fee income required

6. As part of setting our budget for the 2021/22 financial year SMT discussed the emerging financial pressures on the HTA and have incorporated the following material points in setting a budget for the upcoming financial year:

   - Our budget assumes a full staff complement for the 2020/21 financial year.

   - We anticipate cost inflation broadly in line with the current rate of CPI (currently below 1%) and the need for the HTA to mirror pay rises across the public sector, which were on average 2% in 2019/20.

   - We expect Grant in Aid (GIA) from the Department of Health and Social Care to remain at the level received from 2020/21.

   - Following our relocation to 2 Redman Place we expect to see a c20% reduction in net accommodation costs, reducing expenditure in this area by approximately £60k.

   - We have budgeted for the full resumption of our site visit programme from April 2021 and for Board and committee meetings to return to in person meetings from the start of the financial year. Although our ability to commence this activity is at this time, uncertain, we believe it to be prudent to include full costs at this time.

7. Our proposed baseline budget for 2021/22 is unchanged from this current financial year at £5.3m, taking account of the above assumption related to GIA funding from the Department and other funding sources remaining constant, we calculate that the HTA will again need to generate £3.9m of income from fees.

8. We calculate that this sum can be recovered without increasing fees for the 2021/22 financial year.

9. In taking the decision not to increase fees SMT considered the possibility of increasing fees by CPI, which for August 2020 was 0.5%, this would generate c£19k of additional income but can be offset by the savings generated by our relocation. It was felt that any increase above CPI was not warranted this financial year and would be difficult to

justify given the uncertainty regarding next year's activity levels and the issues that some licensed establishments might be facing due to the ongoing restrictions.

Fee levels

10. Current fees are provided at Annex A.

11. It is **recommended** that the Human Tissue Authority maintain the fee structure set out in Annex A.

Next steps

13. The Board is asked to agree the proposed fees for 2021/22. We aim to publish these fees on our website for all stakeholders in December 2020.

Annex A. Current HTA License Fees

Public Display	
Main fee	£1,315
Each of satellites 1-4	£325
Each of satellites 5+	£165

Organ Donation and Transplantation	
Main fee	£4,225
Plus 1-2 organ types	
Fee level 1	£3,155
Plus 3 organ types	
Fee level 2	£6,295
Plus 4 organ types	
Fee level 3	£8,385
Plus 5+ organ types	
Fee level 4	£10,400
Organisation responsible for procuring organs	£30,215

Post Mortem	
Main fee	£3,420
PM examination – Main Site	£2,405
PM examination – Satellite	£1,200
Storage	£345
Removal for a scheduled purpose	£345
Each of satellite 1-4	£1,550
Each of satellite 5+	£805

Research	
Main fee	£3,530
Each of satellite 1-4	£835
Each of satellite 5+	£420

Anatomy	
Main fee	£2,550
Each of satellites 1-4	£410
Each of satellites 5+	£205

Human Application	
Main fee	£5,720
5+ tissue types	£2,030
Processing	£3,045
Procurement	£1,070
Testing	£1,070
Storage	£1,070
Distribution	£540
Import	£1,070
Export	£540
Each of satellite 1-4	£3,640
Each of satellite 5+	£2,030

Application Fees

Fees	
All sectors excluding Human Application	
Main site	£3,225
Satellite	£825
Human Application	
Main site	£4,160
Satellite	£885

Board paper

Date	5 November 2020	**Paper reference**	HTA (28/20)
Agenda item	12	**Author**	Louise Dineley, Director of Data, Technology and Development
Protective Marking	OFFICIAL		

HTA's Contingency Arrangements in Response to COVID-19

Purpose of paper

1. This paper aims to provide an update to the Board on the HTA's Contingency Arrangements and state of readiness in response to the ongoing pandemic.

Decision-making to date

2. The HTA's contingency arrangements in response to COVID-19 continue to reflect those previously shared and agreed with the Board in April 2020.

Action required

3. The Board is asked to note the paper.

Background

4. Since March 2020, the HTA has been adapting its working practices to maintain and support the UK's response to the COVID-19 pandemic. The HTA's response had been two fold; firstly considering how through its regulatory activities and responsibilities it could support the national response to the pandemic; and secondly, reviewing its working practices to ensure it continues to operate and deliver its regulatory functions whilst adapting to the changing operating environment.

Reflecting on Changes since March 2020

5.   Over the last six months, the HTA implemented a number of changes as part of its immediate response to the pandemic and as part of its ongoing response throughout quarters one and two 2020/21. These changes have included:

Support to licensed establishments and maintaining a response to COVID-19:

- Publication of updated guidance to all sectors on the response to COVID-19.   This guidance has been subsequently reviewed and updated.
- Introduction and implementation of emergency mortuary licensing provision.   This included support and guidance for the establishment of additional temporary body storage facilities.
- Engagement with the sectors and licensed establishments as part of ongoing regulatory oversight.
- Provision of subject matter expertise through contribution to advice, guidance and programmes as part of the national response to the pandemic.
- Suspension of routine inspections in all sectors.   This has minimised the regulatory activity and asks on licensed establishments so not to detract from any response to coronavirus.

Internal changes:

- Re prioritised Business plan and deliverables in quarters one and two
- Adoption of remote working across the whole organisation.
- Introduction of supplementary guidance to support flexible working arrangements
- Distribution of supplementary IT equipment to ensure effective home working
- Adapting our regulatory approach to support ongoing oversight of risk
- Identification of priority activities to be protected and maintained through prioritised resource deployment and ongoing contingency planning
- Expedited implementation and adoption of Microsoft 365 and cloud migration.
- Tiered well-being programme for staff incorporating regular check ins, a focus on mental health and wellbeing and access to supportive services including the Employee Assistance Programme and targeted support for those identified through risk assessments as requiring additional or enhanced support or access to services.
- Contingency planning within the HTA workforce model to ensure cover and support to roles, functions and in the event of large-scale absence.

6.   The introduction of these changes has not been without challenges. For example, some staff experienced significant challenges in adjusting to home working in the early weeks of lockdown. There were many reasons for this, for some it was balancing work and home life, the provision of childcare and home schooling, the change in routine including the lack of a dedicated workspace and the sense of isolation through shielding and or living alone.   In addition to the physical adjustments, a number of staff experienced

emotional stress and challenge, often related to understanding the implications of the pandemic for themselves and their families.

7. The longer-term consequences of the pandemic have also been raised by staff concerned about the risk of redundancy. To date the HTA has neither furloughed any staff nor, in the year to date, needed to consider redundancy as a response to the challenges it faces. Our income position remains positive and we have not seen any material changes to the number of licensed establishments or their ability to pay. Monitoring our financial position will be a key component of our future business planning and the continued flexibility of staff will help to minimise any redundancy risk in the future.

8. The capability and resilience of the organisation to deliver at speed, demonstrated the HTA's ability to prioritise and to adjust with agility to the changing external conditions. This agility was reflected in a move from annual business planning to quarterly planning in response to the immediate needs of both the staff and stakeholders. There was an early recognition of the need to be flexible with resources to meet new challenging demands. The suspension of establishment inspections resulted in a reduced workload for Regulation Managers. Some Regulation Managers and Transplant Officers have taken on new tasks, e.g. working in a new area (Post-mortem sector or licensing) or contributed to the project to establish virtual regulatory assessments for each sector.

9. The need to be more flexible has presented some challenges and identified a key learning point around the need to strengthen our understanding of resource planning and deployment.

10. Communication has played a key part in our contingency arrangements. The move to remote working highlighted the importance of clear messages, regular briefings and also replicating the informal kitchen catch ups or corridor conversations. As a result, we developed a number of different routes to inform and engage staff in decisions that were being made, updates on changes as well as listening to how they were feeling or concerns that they may have. Using new and existing channels our communication included:

- The Chief Executive's Monday all staff briefing and Friday message
- SMT & HTAMG daily SitReps
- Daily virtual morning coffee and afternoon team sessions (alternating)
- Weekly SMT drop in sessions
- Social Committee events – a local quiz night to celebrating national events

Preparedness for– the next six months

11. Throughout the summer months, the HTA has continued to monitor and reflect on the contingency arrangements it has had in place and its preparedness of a further increase

in infection rates and extension of restrictions. In recent weeks this scenario has started to emerge.

12. Our experiences and response to the first wave of the pandemic has provided the opportunity for learning, reflecting on what has worked well and where further improvements may be made. The HTA is content that its overall contingency planning remains valid. In readiness for the coming months and a potential protracted period of the pandemic over the winter months, a number of actions have been identified. These include:

- A review of existing COVID-19 guidance to sectors, updating as necessary
- Ongoing improvement to licensing arrangements for example:
  - Application process for new licenses to support COVID-19 related activity
  - Establishing a renewal process for emergency mortuary licenses issued in quarter one
- Further support to staff in the provision of homeworking equipment as well as the availability of a COVID-19 compliant workspace from January 2021. Whilst the current government guidance and HTA approach is for home working only, this space will be available for those that can, and would prefer, to travel to an office when the current situation changes.
- Formal adoption of flexible working arrangements for staff requiring additional flexibility in the working day for caring responsibilities.
- Ongoing support to staff and their well-being through the winter months through a range of activities from wellbeing assessments to personalised support programmes.

Looking Forward – longer term

13. We are beginning our planning for the next business year; this will include detailed consideration of how we will use these lessons learned to inform our longer term strategic and operational plans and processes. Our Development Programme will look at how we might reimagine our approach to regulation through site visits and develop systems and processes that are resilient and able to be operated remotely.

14. We will continue to monitor our regulatory landscape for changing business models and the potential impact for our resources and income. Our income position is currently good, but our reliance on licence fees to fund operations means we are susceptible to small changes in the size the sector we regulate.