Ninety-first Meeting of the Human Tissue Authority

Date 6 February 2020
Time 10.00 – 15.00
Venue Viceroy Suite, The Amba Hotel, Grosvenor, 101 Buckingham Palace Road, London SW1W 0SJ

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 7 November 2019 meeting	HTA (35/19)
4.	Matters arising from 7 November 2019 meeting	Oral
	Regular Reporting	
5.	Chair's Report	Oral
6.	Chief Executive's Report	HTA (01/20)
7.	Delivery Report – Quarter Three 2019/20	HTA (02/20)
8.	Development Report – Quarter Three 2019/20	HTA (03/20)
9.	Deployment Report – Quarter Three 2019/20	HTA (04/20)
	Committee and Advisory Group Reporting	
10.	Audit and Risk Assurance Committee	Oral
11.	Remuneration Committee (RemCo)	Oral
	Policy Issues	
12.	Public Guide to Code of Practice F	HTA (05/20)
13.	Deemed Consent- Outline of the Consultation Response and next steps	HTA (06/20)
14.	HTA Office Re-location	Oral
15.	EU Exit update	Oral
	Any Other Business	
16.	AOB	Oral
	Lunch	

Meeting close 12.30
Lunch – 12.30- 13.20 (Member opportunity for IT support)

Afternoon Training Session 13.20 – 14.00

Insight into the role of the HRA

Minutes of the ninetieth meeting of the Human Tissue Authority

Date 7 November 2019

Venue Viceroy Suite, The Grosvenor Hotel, 101 Buckingham Palace Road, SW1W 0SJ

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Present	
Members Dr. Stuart Dollow Amanda Gibbon Prof. Andrew (Andy) Hall William (Bill) Horne (Interim Chair) Glenn Houston Prof. Penney Lewis Bishop Graham Usher Dr. Lorna Williamson, OBE Prof. Anthony Warrens Prof. Gary Crowe **Apologies** Dr. Hossam Abdalla Dr. Charmaine Griffiths	**In attendance** Allan Marriott-Smith (Chief Executive) Nicolette (Nicky) Harrison (Director of Regulation) Richard Sydee (Director of Resources) Louise Dineley, (Director of Data, Development and Technology) Jess Porter (Head of Regulation, ODT) (item 13/14) Ruth Joyce, (Senior Policy Manager) (item 13) Amy Thomas (Head of Development) Nima Sharma (Board Secretary; minute taking) **Observers** Jeremy Mean, Deputy Director, DHSC Dr. Maeve McRory, Head of Development

Item	Title	Action
Item 1	**Welcome and apologies**	
	1. Bill Horne (the Interim Chair) welcomed Members, attendees and observers to the ninetieth meeting of the Human Tissue Authority (HTA). 2. The Chair welcomed Jeremy Mean, Dr. Maeve McRory, Professor Gary Crowe, Louise Dineley and Dr Amy Thomas to	

	the meeting. There were apologies received from Dr. Charmaine Griffiths and Dr Hossam Abdalla.	
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 18th July 2019 meeting [HTA 26/19]**	
	4. The Chair requested Members' comments on the minutes for factual accuracy. There were no further comments made during the meeting. 5. Members agreed to approve the minutes.	
Item 4	**Matters Arising from 18th July 2019 Meeting**	
	6. The Chair noted that all actions from the 18 July 2019 Authority meeting were resolved, ongoing in nature or would be addressed during the meeting. 7. In particular, the Chair noted that actions one, four, five, eight and twelve are complete and actions nine and eleven would be addressed during the meeting and that actions two, three, six, ten and thirteen would be reported on at the Authority meeting in February. 8. The Chair informed Members that the Executive made a decision not to take action seven forward, as Serious Adverse Events and Reactions (SAEARs) affecting living donation cases are so rare that there is a risk that distinguishing them in the SAEARs reporting in the Delivery Report may risk identification of individuals or individual cases. 9. Amanda Gibbon noted the risks associated with this information not being available to the Authority. She requested that the Executive reconsiders how this information might be provided to the Authority. She questioned whether the Transplant Advisory Group could review this information, possibly in terms of any high-level trends. **Action 1: The Executive to consider its approach to sharing information on SAEARs arising in living donor cases.**	**ANH**

Item 6	**Chair's Report [Oral]**	
	10. The Chair provided an update to Members on a number of items. He informed Members that: - he had spoken with Dr. Hossam Abdalla, passing on the best wishes of all those in the Authority; - he had attended the Audit and Risk Assurance Committee (ARAC) and Stakeholders and Fees Group (SFG) meetings; - he had been involved in interviews to recruit to the new Director of Data, Technology and Development post. 11. The Chair congratulated Professor Penney Lewis on her appointment as the new Law Commissioner for Criminal Law. 12. The Chair also noted that the two new Authority Members have been in post since 4 September and that the new HTA Chair will be in post from 18 November 2019. He also reported that he had conducted handover discussions with the new Chair. 13. The Chair also thanked all those who were in attendance at the HTA Conference as well as the Communications team and Speakers. 14. The Authority noted the content of this update.	
Item 7	**Chief Executive's Report [HTA 27/19]**	
	15. Allan Marriott-Smith presented this item and introduced the report. 16. Allan Marriott-Smith informed Members that the VAT liability matter has now been resolved and has resulted in additional funds becoming available during this financial year. He informed Members that the Executive will be considering using some of the funds to undertake cloud migration which the Head of Business Technology is leading on. He highlighted that the ARAC has been focussed on cyber security and records management. 17. He noted that an Interim Project Manager and Interim HR Advisor will be recruited, to provide support to the Head of HR which will enable her to focus her attention on preparing for the office re-location. 18. Members were informed that the Head of Development is undertaking some work on the better allocation of resource to	

	regulatory risk. The emerging findings following this work will be a theme during the Strategy Away Day in January 2020. 19. Members were informed that the work to refresh HTA values is almost complete and will also be reviewed by the Authority at the Strategy Away Day in January 2020. 20. Members were updated on the outcomes of the recent (Quarter two) Quarterly Accountability Meeting between the Department of Health and Social Care (DHSC) and HTA and that the DHSC were assured on the HTA's preparations for EU Exit. 21. AMS updated Members about a review that was undertaken of the HTA's Freedom of Information Act process (FOIA), following the handling of an FOI request which resulted in the requester making a complaint to the HTA. A lessons learnt meeting will be undertaken. Members suggested that the HTA could explore whether the arrangement with the HFEA could be extended to include HFEA undertaking complaint reviews on behalf of the HTA and vice versa. 22. Members were provided with an update on the HTA's progress with the office relocation and were informed that the Director of Resources chairs a working group on this. The Authority agreed that the relocation is a significant risk to the HTA and one that is currently overseen by ARAC who will be undertaking a deep dive at its January 2020 meeting. 23. The Authority noted the content of this report.	
Item 8	**Delivery Report- Quarter Two 2019/20 [HTA 28/19]**	
	24. Nicky Harrison presented this item and introduced the report. 25. Nicky introduced the new Delivery Report and associated annexes and noted that the information contained in annex B would in future be published in the HTA's publication scheme and made available on the HTA's website. She requested that Members share their views on the new-style delivery report with her. 26. She informed Members that a lighter inspection schedule was in place for quarter three to accommodate Brexit planning activities. She highlighted that a new site visit inspection report template is now in place and that the Regulation Manager (RM) -Training, has been responsible for training all RMs in the new style report. Nicky welcomed feedback from Members on the new template.	

	Members questioned whether there is any value in the RM-Training role being extended beyond the 12 month trial period. The Executive confirmed that this was due to be reviewed in the New Year and an update will be provided in the next quarter's report. 27. ANH noted that the focus of demand-led activity tended to vary between quarters. Over the previous quarter, a number of investigations had been undertaken across most sectors. She added that with the new Head of Planning and Performance now having started, the Executive is looking at time spent on activities and how unplanned activity should best be accommodated within our planning framework. 28. Nicky specifically drew attention to the fact that the enquiries KPI was given a red RAG rating as only 93% of enquiries were answered within 10 working days. She added that it might have been considered that an amber rating would have been more appropriate given the narrow margin by which the KPI was not met, however this KPI was currently based on met / not met criteria on a month-by-month basis. The Head of Performance and Planning will be reviewing all KPIs as part of the development of next year's business plan. 29. Stuart Dollow questioned whether the 10 working day turnaround includes a completion of a response or acknowledgement of an enquiry. There was agreement by the Executive and Members that if an enquiry is identified as being complex and therefore cannot be answered within 10 days, that it would be reasonable that an acknowledgement of the enquiry is sent within 10 working days informing the enquirer that a full response would follow. Nicky informed Members that she would confirm whether there is data available to establish if, on a complex enquiry, a holding response is issued within the 10 working days. 30. Nicky also pointed out that Members might note a discrepancy between the number of Regulatory Decision Making (RDMs) in the HA sector in the narrative compared to the table. This had arisen as two RDMs related to one case and had been counted as two in one place and as one in the other. The Authority noted this. 31. Members also noted that there was a spike in body donation enquiries and wanted to find out why this was the case, however, the Executive informed Members that this spike was not attributable to anything in particular. 32. Nicky informed Members that the two novel transplants had been approved. Whilst Members noted and agreed with the decision	

	for these to have been dealt with as panel cases, they questioned whether the Executive had a policy in place which sets out the the criteria such cases must meet in order to be treated as novel along with the circumstances under which these cases are referred to Panel for consideration. 33. Members noted that page 53 includes information on HTA Reportable Incidents and questioned how (and by whom) the data is reviewed. ANH informed Members that incident data is analysed operationally by the relevant Head of Regulation and the HTARI group and trends are also considered by the Histopathology Working Group (HWG). Members suggested that Statistical Process Control (SPC) techniques could be used. Nicky agreed to look into this. 34. The Authority noted the content of the report along with the change in its format. **Action 2: The Executive to review the relevant policy to ensure it is clear on the criteria to be met for Panel consideration of a novel transplant case.** **Action 3: The Executive to consider using statistical process control techniques in reviewing incident data, such as for HTARIs.**	**ANH** **ANH**
Item 9	**Development Report- Quarter Two 2019/20 [HTA 29/19]**	
	35. Allan Marriott-Smith presented the paper to Members. 36. He informed Members that quarter two has been a busy period due to Brexit planning as well as the work being carried out in preparation for the Deemed Consent legislation. 37. Members were asked to note the ongoing work involving migration to the cloud and that the issues with the remote desktop that were being experienced prior to this meeting were not associated with the migration. 38. The Authority noted the content of this report.	
Item 10	**Deployment Report- Quarter Two 2019/20 [HTA 30/19]**	
	39. Allan Marriott-Smith and Richard Sydee presented this item and introduced the report. 40. AMS provided a follow up on action taken since the stress survey was undertaken. He informed Members that the Head of	

	Planning and Performance will also be responsible for improvements in planning and monitoring workloads. 41. RS provided an update on the release of VAT accrual, which has resulted in £300,000 being released into the accounts and confirmed that there was a material underspend which was as a result of staff vacancies in the first half of the year. 42. RS also asked Members to note that there has been a reduction in HA license fee income due to the number of revocations, but that there has been an increase in the number of license applications. 43. The Authority noted the content of this paper.	
Item 11	**Stakeholder and Fees Group (SFG) Update [Oral]**	
	44. The Chair provided an update to Members following the SFG meeting. 45. He informed Members that the Group was supportive of the proposed changes to the Fees structure. 46. He updated Members on the British Medical Association's (BMA) motion at its annual congress to campaign for the removal of blocks and slides from the scope of Human Tissue Act. 47. He informed Members that there was discussion about, EU Exit, Deemed consent, Digital Communications, Post Mortem Licensing Standards, better coordination of regulatory alerts and consent requirements in research 48. The Authority noted this update.	
Item 12	**Audit and Risk Assurance Committee Update [Oral]**	
	49. Amanda Gibbon provided an update to Members. 50. She informed Members that: - Dr Charmaine Griffiths attended as an observer during the meeting. - progress has been made with regards to actions arising	

	following internal audits. - the new audit report, Utilisation of Capabilities was given a moderate assurance with six medium recommendations. The recommendations were around recording risks, skills audit and register of key roles. - good progress has been made with regards to the Records Management audit and that the Director of Data, Technology and Development will be undertaking the role of Departmental Records Officer. There are areas that will need to be taken further. - a deep dive was undertaken focussing on new license fees. - good progress has been made with the HA risk project. - the Head of Finance has drafted the Counter Fraud Strategy. - the Reserves Policy will be reviewed given that approval was not forthcoming for the use of reserves as part of organisational transformation. 51. The Authority noted the content of this update.	
Item 13	**Transplant Advisory Group [Oral]**	
	52. Professor Anthony Warrens provided an update to Members. 53. He informed Members that: - a significant amount of time was spent discussing deemed consent and Code F. - the group discussed the two bone marrow cases which proceeded without HTA approval. Extensive discussions took place about the measures that have been put place to avoid this happening again. - an update had been provided on the Independent Assessor (IA) sustainability project. 54. Members questioned whether the statisticical risk of death of the donor in kidney transplants is for the UK only or wider. It was noted that this was a worldwide statistic. 55. The Authority noted the content of the update.	

Item 14	**Code of Practice F for Deemed Consent in England Approval [HTA 32/19]**	
	56. Jess Porter and Ruth Joyce presented this item. 57. Jess confirmed that significant work has been undertaken in the re-drafting of Code F and that Members' comments will be taken forward. 58. Jess informed Members that there are a number of areas in the Code which still require legal advice, in particular, the scenario where a Nominated Representative is not contactable. Following the legal advice received, Members agreed that where a Nominated Representative was not contactable, consent would be sought from a person in a qualifying relationship. 59. Professor Penney Lewis highlighted that in Code A such a nomination is disregarded and consent can be given by a person in a Qualifying Relationship. 60. Members highlighted that paragraph 87 appears to contradict paragraph 80 which is about expressed consent. PL shared her concerns with Members and stressed the importance of ensuring that deemed consent is not perceived to be a lesser form of consent than expressed consent. 61. Members raised questions about whether the HTA should set out that the Code would be reviewed in future. It was agreed during the meeting that this would not need documenting in the Code itself. 62. Members informed the Executive that paragraph 66b, which is about a significant period of lacking capacity, would need further work to provide more clarity. 63. Jess confirmed that Code F will need to undergo full legal review before being shared with the Department of Health and Social Care (DHSC) in the first week of December. Members confirmed they were content for the Code to be signed off via correspondence, provided that the relevant amendments are appropriately flagged. 64. Members requested paragraph 177d be re-worded due to the	

	use of double negative phrases. 65. Members thanked Jess for incorporating changes. 66. The Authority noted the content of this paper. **Action 4: Code F to be reviewed in light of the comments received by Members during the meeting and for the Code to receive formal sign-off from the Authority via email.**	**ANH**
Item 15	**Out of Hours Approval for Living Organ Donation Cases [HTA 33/19]**	
	67. Jess Porter presented this paper to the Authority. 68. Members commented that the paper was very clearly written setting out the proposed recommendations and noted the Executive's decision not to take forward any changes to the process for managing out of hours approvals at present. 69. Although some Members feel that the current process is appropriate, some Members emphasised that this responsibility perhaps sits better with the officers who routinely consider these cases for approval. However, Members were also mindful that this could place a disproportionate burden on the team. 70. Some Members still felt that there would be some merit in the Executive exploring the potential of remunerating staff for their involvement in the out of hours rota. 71. Lorna Williamson suggested that the involvement of staff in the out of hours rota would need to be carried out by the most experienced staff, however, Members felt that this may prove difficult for non LDAT staff given the very few out of hours cases received on an annual basis. As for the LDAT staff they are the most experienced in dealing with the category of cases that will be received out of hours. 72. The Chair concluded by requesting that the Executive explores the options for remuneration and to provide a proposal at a future Authority Meeting. 73. The Authority noted the content of this paper. **Action 5: A proposal to be brought to a future Authority meeting on the options for remunerating staff involved in the out of hours rota.**	**ANH**

Item 16	**EU Exit [Oral]**	
	74. Nicky Harrison provided an oral update on this item. 75. She informed Members that the HTA has stood down EU exit related activity and that the HTA has met with the DHSC about Incident Management. 76. Members were informed that the EU Exit Project Manager who will be in post until January 2020 is supporting her with this work and that there is a plan for activities for the transition period. 77. The DHSC has commended the HTA for the level of effort made in preparation for EU Exit and the chair thanked those involved for the work that had been undertaken 78. The Authority noted the content of this update.	
Item 17	**Licence Fees 2020/21 [HTA 34/19]**	
	79. Richard Sydee presented this paper. 80. He informed Members that there was a date error in the paper at paragraph three, which stated, 2018 rather than 2019. He apologised for the error. 81. He referred Members to paragraph seven of the paper which sets out the final recommendations that SMT had proposed. It was agreed at ARAC that a complex satellite site charge in the HA sector be withdrawn as it is difficult to define complexity within the sector, however the issue of consolidation of licenses under satellite licenses requires further work. 82. He explained that the Third Party Agreement (TPA) area is complex and as yet the HTA is unclear about how it should be regulated and charged for. Members were informed that that the focus of the fees review would be based on activity and risk. 83. Members agreed that a four percent increase is the right amount in terms of the HTA's needs, including any contingency and working on the basis of assumed underspending on staff costs. Members agreed with the Executive's proposal not to raise fees by six percent. 84. Members questioned whether the HTA's office re-location would	

	have an impact on the HTA's expenditure. Richard confirmed the predicted re-location costs are relatively low, however, there is additional resource required involving project management. He informed Members that at present the HTA is uncertain about the amount needed and that this would be captured in the business case. 85. The Chair concluded by requesting Members make a decision on whether a four percent increase was appropriate. Members accepted the recommendation to increase fees by four percent. 86. The Authority noted the content of this paper.	
Item 18	**AOB [Oral]**	
	87. The Chair asked Members and the Executive if there was any other Business. Members noted Bill's contribution as Interim Chair and thanked him for all of his support. 88. There was no other business.	

HTA Board paper

Date	6 February 2020	**Paper reference**	HTA (01/20)
Agenda item	6	**Author**	Allan Marriott-Smith Chief Executive
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Chief Executive's Report

Background

1. This paper provides an overall assessment of the strategic risks currently facing the HTA as set out in **Annex A**. The paper also reports on other issues of strategic interest emerging since the last meeting on 7 November 2019.

Decision-making to date

2. This report was approved by the CEO on 27 January 2020.

Action required

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

Overview of Strategic Risks

4. In its assessment of risk in January, the senior management team concluded that there was upward pressure on ***Risk 4*** - ***Failure to utilise people, data and business technology capabilities effectively.*** It is proving difficult to recruit the right calibre of candidate for the permanent roles of project manager and business analyst within current pay bands. These roles support the delivery of the HTA Development Programme, and will, if unmitigated over time, present risk to its achievement. This risk is being mitigated in the short term by looking to recruit interim resources. More formal work on workforce and succession planning which will commence early in the new business year.

5. In January, all other strategic risks were assessed as being stable.

6. Other strategic risk drivers to note in January include the assessments made by internal audit during the previous quarter in relation to business continuity and critical incident response planning and the uncertainty related to resource needs for EU exit over the remainder of the calendar year. Further information on these issues will be outlined during the meeting.

Other Issues

HTA Strategy away day

7. The HTA Strategy Away day took place on 21 January 2020 and focussed on the progress made so far in achieving the HTA's Strategy that was originally set out for the three years beginning April 2018, the priorities for the final year of the Strategy, and the key strategic risks facing the HTA.

8. The Board was provided with, an, overview of the HTA's operating environment through a pestle analysis, introduction to the prioritisation of activities and an overview of the HTA's tools to measure risk. The day also included an item which focussed on scenario modelling to identify the Board's tolerance for risk as well as an updated priorities exercise to enable Members to consider what areas of must be prioritised for the next 12 months. The Board were also given an introduction to the HTA's values following a review and refresh undertaken by the Executive in quarter one and two and were asked to provide their feedback on the new values.

9. The key matters agreed during the day were:

- an affirmation of the need to maintain core functions and not diminish our critical capabilities during the next 18 months;
- the Development activity that needs to be prioritised over the next 18 months agreed priorities;
- that work under the People Strategy should focus on those activities and policies that support remote working and the office move, including a focus on communication of change;
- that work on the Digital, Data and Technology Strategy should support remote working and the office move, but that more ambitious change should not be attempted until 2021/22 (subject to funding);
- building on the work undertaken by the Audit and Risk Assurance Committee, the Board will seek to develop a more detailed understanding of strategic risk drivers over the coming twelve months, with a view to more clearly articulating shared risk appetite and tolerance.

Chair Appointment

10. Lynne Berry was appointed by DHSC from the 18 November for a period of three years. She has completed her internal induction and is now in the process of meeting key stakeholders over the coming months.

Annual Conference

11. The HTA's annual conference in November was successful and the HTA received positive feedback. Responding delegates (88 respondents) agreed that the event was a good way to engage with the HTA and that the table hosts were effective. Further information can be found in the Development report at agenda item 8 (HTA 03/20).

Staff Survey

12. The biannual HTA staff survey ran from 18 November to 6 December. The aims of the survey were to better understand employee morale, satisfaction and engagement.

13. A presentation of the survey results and the issues of strategic importance that it raises will be presented during this item at the meeting.

All staff away Day

14. An all staff away day took place on Monday 16 December at the Le Meridian Hotel.

15. The day focussed on the development of the HTA's values statement, the HTA's strategy, business planning, the HR competency framework and the office re-location.

16. Staff engagement on the day was high, and the executive continues to use these quarterly session off site to communicate and engage with staff on the mid to long term changes facing the HTA.

Quarterly Accountability meeting to DHSC

17. The HTA met with DHSC on Thursday 16 January 2020 as part of its regular quarterly accountability arrangements. An oral update on the outcomes will be provided at the meeting.

18. Minutes of the quarter two Accountability meeting on the 10 October 2019 have been circulated with the Board papers for information.

Internal Audit

19. The draft report for Business Continuity and Critical Incident Management was issued in December and discussed at the January ARAC meeting. Internal Audit has been working closely with the HTA to agree recommendations and actions from other recently completed audits. Work has also commenced on audit planning for 2020/21.

Freedom of Information requests

20. Eight requests for information under the Freedom of Information Act (FOIA) were received during quarter three, compared with seven in quarter two. In addition there was one FOI request received which subsequently, on consideration, was deemed not to meet the requirements of an FOI and was handled as a general enquiry. We publish FOIA responses on our website.

21. Over the quarter, the majority of the requests appear to be associated with generating information about HTA internal administration and contracts, while a small minority relate to our regulatory role and findings.

Complaints

22. In quarter three one complaint was received by the HTA in regards to the HTA's involvement in providing advice about a licenced establishment to another regulator as part of an investigation they were undertaking.

23. A lessons learnt exercise based on two recent uses of the complaints policy was completed in November. An action plan has been drafted and discussed with the HTA Management group. This will result in further changes to the complaints policy and all-staff awareness training.

HTA Strategic Risk Register
January 2020

Overview: Risks reflect the strategy for 2019 - 2022. Our highest scored risks are the failure to manage expectations of regulation, which reflects the fast-pace of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively. Our Regulation Manager cadre is now more experienced with all now signed off to lead and support inspections. This has had a mitigating impact on risks 1 and 4. At the beginning of January, six posts are vacant, Project Manager, Business Analyst, Quality and Corporate Governance Manager, Policy, Strategy and Communications Officer, HR Manager and a Regulation Manger. The first two of these roles have proved difficult to fill with suitable candidates. In addition a further 4 vacancies will arise over the next two months and plans are underway to fill these posts The new Director vacancy is now filled, and SMT's leadership capability is now at full strength.

Other notable risks: Internally, planning for no deal EU Exit has been stood down on DHSC advice. The HTA stands ready to support DHSC as required, and at present, it is difficult to assess how much resource will need to be dedicated to EU Exit planning over the remainder of the business year and into 2020/21.

Progress on other development activity slowed as a result of carrying out work relating to EU exit, the opt-out consent Code of Practice. Work is continuing to scope the development priorities for the coming two years. Additional funds have been released as a result of the resolution of a long standing rent dispute. Plans are now well underway to invest these funds in parts of the Development Programme that support our office move and could be delivered in this tight timescale, or which build a foundation for future development. This continues to bring management overhead in terms of oversight and the administrative burden of letting appropriate contacts in short timescales, although this is proving manageable.

DHSC spending controls are likely to place continuing pressures on ALBs to make savings. We have received confirmation of GIA funding for the 2020/21 financial year, but anticipate that we will continue to be unable to access reserves to fund our wider development project ambitions - we will need to consider the options to provide some contingency funding next financial year to enable the completion of the development work we undertake from now until March 2020.

Risk	*Oct 2019*	*Nov 2019*	*Dec 2019*	*Jan 2020*	*Comments*
1 - Failure to regulate appropriately (Risk to Delivery a-d & f and Development a-d)	↓	→	→	→	*A good regulatory framework and processes are in place, with a strong assured position on our key regulatory processes confirmed in the recent internal audit of these processes. Further continuous improvement is planned through mechanisms such as the recently introduced quality forum and the investment in the new one-year role of Regulation Manager - Training. All new Regulation Managers recruited during the preceding year have now been signed-off to lead inspections, increasing the organisation's capacity and strengthening our regulatory capability.* *A range of training activities and the new RM induction programme have been overseen by the new RM-Training. Regular training sessions coupled with work to improve and standardise reporting processes along with an increasing focus on using data and data quality is also improving this area.* *Given the work done to date, we consider the overall risk level is now falling, although we note that churn amongst the Authority, including the Chair, potentially leaves some gaps in oversight and support on regulatory and transformation issues.* *The introduction of the new Inspection Report templates reduces the risk of inconsistencies in reporting which we feel has a positive impact on this risk.*
2 - Failure to manage an incident (Delivery, Development and Deployment)	→	↓	→	→	*Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 2016/17.* *The Critical Incident Plan (CIP) was utilised to manage a building power outage during March 2018 and a regulatory issue in April 2018. Lessons learnt papers were discussed at ARAC, but the incidents were managed well. We have received the final reports from the internal audit review of our Business Continuity and Critical Incident Management arrangements providing moderate levels of assurance in both areas. Actions will be discussed with ARAC in due course and recommendations implemented. Plans for a 'no deal' EU Exit have been halted in line with Government instructions, we believe we are well positioned to respond to emerging instructions as negotiations develop*
3 - Failure to manage expectations of regulation (Risk to Delivery e and Development c)	→	→	→	→	*We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DHSC and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but which may adversely impact on public confidence is challenging. The number of perimeter issue shows no sign of decreasing. These issues and the planning for EU exit continue to occupy regulatory resource. We are conscious that we have staff operating in the front-line roles who may be challenged about our response to issues outside our remit.*
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	↓	↓	→	↑	*We are now using the skills of our more recent recruits more fully. Some specialist posts have been harder to fill successfully. Limited success in recruiting into key roles in combination with new vacancies has increased the pressures on our resources, as a result we have indicated an overall up tick of the risk in this area. Workload and pressure continue to be monitored closely by the management team and an action plan is in place to deal with the recommendations of the stress survey and audit. We achieved our planned position relating to GDPR by the end of March 2019 and have received moderate assurance from internal audit. Good progress has been made on improving our induction procedures and this is being built on by the appointment of the RM-Training, with responsibility for induction, learning and development. We note the upcoming vacancies that will arise across the Regulation and DDT directorates in the new year and the plans to revise job roles and advertise to fill those roles. We will continue to monitor these areas over the next quarter* *Additional funding released as a result of the resolution of the rent dispute means that some funding can be used during this financial year which will support smarter working initiatives and improved data use.*
5 - Insufficient, or ineffective management of, financial resources (Deployment b)	→	→	→	→	*Partial funding from DHSC was secured to cover increase in Employers' Pension contributions for 2019/20 along with non-cash income to cover our depreciation costs. Budget pressures this financial year have been alleviated due to the settlement of a longstanding rent dispute, this has released c£350 of additional funds that can be utilised through to the end of the March 2020.* *The lack of funding for Transformation programme beyond this financial year will limit the activity that can be initiated now was not approved in the current business year.* *We await final confirmation of the GIA settlement for the 2020/21 financial year from DHSC finance colleagues, we hope this will be received in time to inform budget and fees setting for the next financial year, in particular the ongoing funding of the NHS Pension contributions increase is a key concern.* *A recent incident of mandate fraud has led to the strengthening of processes around notification of changes to payment information and their authorisation. This relates to Risk 2 as well as the inclusion of additional IT protocols and awareness briefings.*
6 - Failure to achieve the benefits of the HTA Development Programme (Development objectives a-d)	↓	↓	→	→	*The impact of 'high' recognises that aspects of the programme in particular IT related could have significant impact on the business should service be disrupted. DHSC did not agreed funding for this Programme in the current business year which has delayed the planning and project initiation. Some funding is now available for the remainder of this financial year and we anticipate some progress in implementing necessary change associated with the office relocation.* *The office move project is underway and recruitment of additional PM resources to support detailed planning is being considered, the impact of the move on other activities in the next business year are being accounted for and this remains one of our priority activities for the next year.*

Risks are assessed by using the grid below

Risk scoring matrix

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

Risk Score = Impact x Likelihood

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

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* • *Risk based approach to implementing Import and Coding regulations ahead of 31 March 2018 deadline* • *Failure to deal with regulatory consequences of EU exit* • *Uncertainty regarding the appointments to and composition of the Board.* ***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**	**1**		1	2	3			
						HTA Strategy 2018 to 2021 clearly articulates the HTA's regulatory model					X		Preventative	Authority developed and approved the HTA Strategy	HTA Strategy published in May 2019
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory report made in July 2019
						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.
						Approved HTA Business Plan 2018/19 identifies a balanced programme of regulatory activity and continuous improvement				X	X	X	Preventative	Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department	HTA Business Plan to be published in April and approved by the Department of Health and Social Care
						Well established processes support our core regualtory 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
						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	Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates	Management are aware of limitations in the QMS - HTAMG took a report of proposed improvements in March 2019 and a Quality Forum is now in operation to improve the QMS.
						People									
						Adherence to the HTA People Strategy which has been substantially amended and approved by the Authority				X			Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made at November 2019 Authority meeting
						Training and development of professional competence				X			Preventative	Annual PDPs, RM proposals to SMT	End of year PDP process was completed July 2019.
						Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas				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
						EU Exit									
						Close liaison with DHSC and contingency planning for a range of outcomes including no-deal			Weekly internal Brexit meetings re-started August 2019 focusing on planning for Brexit on 31st October. New HoPP working with ANH and Heads to complete task and resource planning and management for no-deal Brexit in readiness for increased activity from mid-October to end of November. A decision was taken to recruit a temporary contractor to fulfil the role of Brexit Project Manager and coordinator for the expected period of peak activity from the middle of October.				Preventive / Detective / Monitoring	Weekly reporting by ANH to SMT under standing item on SMT agenda. Notes and actions from weekly Brexit meetings. Recruitment of Brexit Project Manager (temporary contractor) has started - interviews started w/c 30/9/19.	Readiness Assessment completed and sent to DHSC August 2019 showed strong assured position across all areas. Brexit Project Manager due to start 15 October. Work has now paused in line with instructions received from DHSC in late December 2019
						Use of existing regulatory model to manage the outcomes of 'no-deal'			Existing regulatory decision making framework and critical incident response plan have been adapted and applied to managing EU Exit planning. We have characterised data sets (including Annual Activity Data) which we are using to inform resource allocation and to inform anticipated decision making.				Detective / Monitoring	We are contributing, via DHSC, to planning around clinical trials involving tissue and cells – this makes sure consistent information is being provided and that we are reaching an appropriate network of stakeholders.	We have looked at which MS tissues and cells are imported from to work out what policy issues may arise because of how the legislation has been interpreted; we have also used data to identify where an incident arises in one establishment, how we would be be able to use our data to work out the extent and/or impact of the issue.
						Board									
						Experienced Authority Member appointed as interim Chair Future appointments pending - have requested that the Department expedite recruitment for Chair and additional members									
									Regulatory model						
									Delivery of Licensing and inspection review projects and outcomes of HA Risk and PM Development work to strengthen our regulatory model. Agreed action plan to end Q1 2019/20 (AMS)	X			Preventative		
									Consideration of Import licenced establishment in HA inspection planning. Establishments assessed in order of existing risk profile and level of activity	X			Preventative		
									Other						
									Strengthening horizon scanning arrangements	X			Preventative		
									Embed Better Regulation initiatives in the regulatory model	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 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	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* • *Consequences of 'no-deal' EU Exit affecting supply routes, staff availability or multiple incidents* ***Effect*** • *Loss of public confidence* • *Reputational damage* • *Legal action against the HTA* • *Intervention by sponsor*	***5***	***3***	Future, should event occur	Filled identified business-critical roles	***3***	***2***		1 X	2	3	Preventative	Monthly reports to HTAMG	Monthly reports on vacancies by the Head of HR to SMT and KPI requiring exception reporting if there are more than two vacancies at the end of each month, although without reference to specific business-critical posts. Last report January 2020.
						Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff				X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Subject to internal audit reported to ARAC in February 2020
						Media handling policy and guidance in place, including regular media training for key staff & Members with relevant scenarios, to supplement media release and enquiries SOPs				X			Preventative	Policy reviewed annually, training specifications Reports on media issues in Delivery Report	
						Accessible lines to take and key messages for likely scenarios				X			Preventative	Documented, incidents reported to Chair and in Delivery Report	Delivery report to Authority meeting May 2019
						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	Policy reviewed by Authority July 2018
						Onward delegation scheme and decision making framework agreed by the Authority				X	X		Preventative	Standing Orders and Authority minutes	SOP reviewed and agreed in 4 May 2017 (next review pending)
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	RDMs summarised in Delivery Report to Authority Meeting in November 2019.
						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 October 2019
						Critical incident response plan regularly reviewed and tested				X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT	CIP was used to manage a power outage during March 2018 and a regulatory incident arising in April 2018
						Evaluate test exercise of incident and feedback to all staff.				X			Preventative		Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018
						Plan to develop and strengthen the relationship with DIs				X			*Preventative*	*Blog and DI training*	*Project on business plan*
						EU exit plans in place			EU Exit planning managed as a project with clear identification of potential issues, reporting triggers and how these will be monitored. Planning for anticipated responses. Ensuring there is a daily cover rota for all expected tasks and roles over the expected peak period from mid-October to end November 2019. Development of Daily SitRep concept to support monitoring over this period with intention of using existing decision-making frameworks to deal with any escalation required. Recruitment of a Brexit Project Manager.					Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting. Updated EU Exit readiness assessment completed in August 2019 and considered by SMT and DHSC. Daily SitRep structure planned and arrangements put in place for their organisation and for monitoring and escalation of arising issues. Completion of daily cover rota with colleagues knowing expectations of their roles over this period. Awareness-raising across HTA at all-staff meeting on 14/10/19. EU exit response planner developed to ensure that if an incident arises, we all know what to do.	EU Exit planning is a standing item on the weekly Senior Management Team Meeting and was covered in detail at the February, May and July Authority Meetings. Mostly green operational readiness assessment reported to DHSC August 2019. Further consideration of HTA's Operational Readiness at SMT on 11/10/19 and assurance on operational readiness to be reported to DHSC by 16/10/19. Work has now paused in line with instructions received from DHSC in late December 2019

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT I	INHERENT L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK I	RESIDUAL RISK L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
3	***Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or misperception of HTA regulatory reach*** ***(Risk to Delivery objective e, and Development c)*** *Risk Owner:* ***Louise Dineley***	***Cause*** ***External factors*** • *No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)* • *Rapidly advancing life sciences* • *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates* • *Introduction of deemed consent for Organ donation in England* • *Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario* ***Matters which certain stakeholder groups believe require review*** • *Scope of relevant material e.g. waste products* • *Licensing requirements e.g. transplantation research* • *Regulation relating to child bone marrow donors* • *Issues raised by emergence of social media e.g. non-related donors* • *Strengthening of civil sanctions for non-compliance* ***Matters which stakeholders/public may expect to be inside regulatory scope*** • *Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure* • *Police holdings* • *Products of conception and fetal remains* • *Data generated from human tissue* • *Funeral directors* • *Forensic research facilities* • *Cryonics* • *Body stores / Taphonomy* • *Imported material* • *Clinical waste* • ***Other*** • *Inadequate stakeholder management* ***Effect*** • *Diminished professional confidence in the adequacy of the legislation*	*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* *X*	*3*	*Monitoring*	*Ongoing log*	*Log in place and reviewed at HTAMG quarterly. New issues identified in causes and effects* *Reviewed by HTAMG in September 2019*
						Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope				*X*			*Preventative/ Detective*	*Stakeholder Group meeting minutes* *Authority minutes (including Public Authority Meeting)* *TAG and HWG meetings*	*Last stakeholder group meeting in October 2019* *Public Authority Meeting in May 2019; Histopathology Working Group January 2019; Transplant Advisory Group May 2019*
						Active management of issues raised by the media – including the development of the HTA position on issues				*X*			*Preventative/ Detective*	*Quarterly reports to Authority on communication (including media) activities*	*Last report to Public Authority Meeting in May 2019*
						Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence					*X*		*Monitoring*	*Quarterly Accountability meetings with DH*	*Full year accountability meeting in May 2019*
						Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance)				*X*			*Preventative*	*Published guidance for particular issues (e.g. pregnancy remains, and cord blood)*	*Pregnancy remains guidance published March 2015* *Cord blood guidance issued in March 2016 Guidance is still current.* *Cryopreservation information for public published September 2018*
						Clear view of use of s.15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge				*X*			*Preventative*	*Duty and its uses understood by SMT and Chair*	*Letter to Minister re. import and consent requirements for public display* *Advice and guidance continues to be provided.*
						Legal advice now gives a clearer view of our Schedule 2, s. 20 powers				*X*			*Preventative*	*Legal advice to be followed*	*Legal advice September 2016. No change to position.*
						Codes of practice and standards – provide greater clarity on matters inside and outside of regulatory scope were published **April 2017.** Circulation of principles within Code A to wider stakeholders was undertaken Quarter 3 2017/18				*X*			*Preventative*	*Codes published on website*	*Supplementary guidance on PM standard on traceability issued Feb 2019*
						Partial implementation of triennial review recommendations **March 2017**				*X*			*Preventative and remedial*	*Recommendations form part of business plan*	*Good progress, most complete with only benchmarking to be finalised*
						Public research - gaining a better understanding of public confidence and the factors which impact it - **complete Q2 2017/18**				*X*			*Preventative*		*Authority undertook review of headline messages at strategic awayday October 2017.* *Public forum and review of public guides*
						Proactive horizon scanning and development of policy in emerging/complex areas Project complete Q3 2017, now business as usual				*X*			*Preventative*	*HTAMG Minutes*	*Horizon scanning map in use and reviewed quarterly by HTAMG* *Horizon scanning standard agenda item at all stakeholder group, TAG, HWG*
									Deliver programme of work to improve relationships with licensed establishments	*X*			*Preventative*	*Programme monitored by SMT and HTAMG*	*Programme underway* *Licensed establishment engagement programme established to inform work* *New ToR for internal group to agree focus for next business year*

		• *Reduced public confidence in regulation of matters relating to human tissue* • *Reputational damage*					*Regular meetings with DHSC policy team and attendance at other departmental meetings (ALB delivery partners, ORG, Comms sub-group) to inform planning for EU Exit and plan in place, including for a 'no-deal' scenario*	*x*			*Preventative*	*Meetings diarised and actions recorded. Internal EU Exit lead identified. Quarterly updates provided to Authority in Development report, and substantive paper at February 2019 meeting*	*On track, but uncertainty remains Guidance to sector published Feb19 ORC assessment of preparedness as green* *Extension period agreed to 31 October 2019; frequency of meetings reduced pending outcome of further Govt negotiations*

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4	***Failure to utilise people, data and business technology capabilities effectively*** ***(Risk to Delivery objectives a-e, Development a-d Deployment a, c and d)*** *Risk Owner:* ***Louise Dineley***	• ***Cause*** *Lack of knowledge about individuals' expertise* • *Poor job and organisational design resulting in skills being under used* • *Poor line management practices* • *Poor project management practices* • *Poor leadership from SMT and Heads* • *Data holdings poorly managed and under-exploited* • *Inadequate business technology or training in the technology available* • *Lack of ring-fenced resource for 'no-deal' EU Exit* ***Effect*** • *Poor deployment of staff leading to inefficient working* • *Disaffected staff* • *Increased turnover leading to loss of staff* • *Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed* • *Poor use of technology resulting in inefficient ways of working* • *Inadequate balance between serving Delivery and Development objectives*	*4*	*4*		***People***	*4*	*3*		*1*	*2*	*3*			
						Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle				X	X		Preventative/ Monitoring	QMS reminders as policies due for review. SMT review of all revised policies	Regular review cycle recommenced in late summer
						Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review) Standard objectives for all line managers				X	X		Preventative/ Monitoring	PDP guidance reviewed annually and approved by SMT, newly introduced countersigning officer check	Guidance issued April 2019. End of year guidance has been issued and process commenced.
						Regular review of HTA organisational structure and job descriptions				X	X		Preventative	Recruiting to the currently agreed organisational structure and approved job descriptions	Job descriptions reviewed as posts become vacant and recruitment to new vacant posts almost complete.
						Feedback from HTA people about work, management and leadership				X	X		Monitoring/ Detective	Staff survey, exit interviews, staff forum (attended by SMT Member and Head of HR)	Staff Survey completed Janauary 2020, action plan to be developed in Q4. ARAC chair regularly discusses staff issues with chair of staff forum.
						Revised People Strategy 2019 to 2021				X			Preventative/ Monitoring	Authority approval of the Strategy	Authority approved the Strategy at its meeting in February 2019.
						Data									
						Data relating to establishments securely stored with the Customer Relationship Management System (CRM)				X		X	Preventative/ Monitoring	Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security.	CRM upgrade completed successfully in March 2019
						Appropriate procedures to manage personal data inlcuding GDPR compliance.				X		X	Preventative/ Monitoring	Internal audit on GDPR compliance provided moderate assurance.	Internal audit report in March 2019.
						Business technology									
						Staff training in key business systems				X			Preventative	Systems training forms part of the induction process for new starters	Ongoing records of all new starters trained in key business systems
						IT systems protected and assurances received from 3rd party suppliers that protection is up to date				X	X	X	Preventative/ Monitoring	Quarterly assurance reports from suppliers. MontAMSy operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2019
									Business technology						
									Identify refresher training and targeted software specific training needs.	X			Preventative		

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY I	INHERENT RISK PRIORITY L	PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY I	RESIDUAL RISK PRIORITY L	ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE 1	LINE OF DEFENCE 2	LINE OF DEFENCE 3	TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
5	*Insufficient, or ineffective management of, financial resources* *(Risk to Deployment objective b* *Risk Owner:* *Richard Sydee*	***Cause*** • *Fee payers unable to pay licence fees* • *The number of licenced establishments changes, leading to reduced fee income* • *Management fail to set licence fees at a level that recover sufficient income to meet resource requirements* • *Failure to estimate resource required to meet our regulatory activity* • *Poor budget and/or cash-flow management* • *Unexpected increases in regulatory responsibilities* • *Unforeseeable price increases / reductions in GIA* • *Fraudulent activity detected too late* ***Effect*** • *Payments to suppliers and/or staff delayed* • *Compensatory reductions in staff and other expenditure budgets* • *Increased licence fees* • *Requests for further public funding* • *Draw on reserves* • *Failure to adhere to Cabinet Office Functional Standards* ***Leading to:*** • *Inability to deliver operations and carry out statutory remit* • *Reputational damage and non payment of fees*	*5*	*4*	Ongoing	Budget management framework to control and review spend and take early action	**2**	**3**		**X**	**X**		All	Budgetary control policy reviewed annually and agreed by SMT	Last review January 2019
						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 April 2019
						Licence fee modelling							Preventative	Annual update to fees model	Update agreed by the Authority November 2019 meeting
						Rigorous debt recovery procedure				**X**			Preventative	Monthly finance reports to SMT and quarterly to Authority	Last quarterly report November 2019
						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 2019
						Prioritisation when work requirements change				**X**			Preventative	Agreed business plan, monthly HTAMG and SMT reports	Last HTAMG report October 2019 Last SMT update January 2020
						Fees model provides cost/income information for planning				**X**			Preventative	Annual review of fees model, reported to SMT and Authority	Update agreed by the Authority November 2019.
						Annual external audit						**X**	Detective	NAO report annually	Last report in June 2019 - clean opinion
									Monitoring of income and expenditure (RS) **Ongoing**			**X**	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report January 2020
									Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) **Ongoing**	**X**	**X**		Detective	Quarterly Finance Directors and Accountability meetings	FD from NHS Resolution, HRA, NICE and CQC maintain contact over common issues 2019/20 - last met July 2019 DHSC Finance wrote in September indicating confirmation of GIA funding sometime in October 2019 Confirmation of 2020/21 GIA recovered in December 2019
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	**X**	**X**		Preventative		

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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			4	4							
						SMT experience of organisational change, programme and project management				X			Preventative	*Recruitment of an HTA Programme Director*	*The Director of Data, Technology and Development appointed in October 2019 will act as Programme Director.*
						HTA approach to the management of change projects (underpinned by PRINCE2)				X			Preventative		
						A number of trained project managers among HTA staff				X			Preventative		
						Experience of procurement and contract management				X			Preventative		
						Existing mechanisms for engaging staff				X			Preventative		
						Well established corporate governance arrangements and financial controls					X		Monitoring	*Internal audit of key controls*	*Assurance provided by Internal Audit of adequacy of key financial controls*
						Agreement to a phased delivery approach to avoid all or nothing investment and align with available funding				X			Preventative		
						Obtain external advice on programme design and implementation				X			Preventative	*Advice provided by PPL to SMT in April 2019*	
									Implementation of external advice on programme design and governance	X			Preventative	*PPL presentation to SMT April 2019*	
									Embed Benefits Realisation Management methodology within programme	X			Preventative		
									Introduce a Programme Management Office	X			Preventative		
									Authority approval to proceed at key Gateway decision points		X		Monitoring		
									Act on the formal training needs analysis undertaken for the HTA more widely to identify and improve the level of internal capability to deliver the programme	X			Preventative	*Formal training needs analysis data provided to HTA April 2019*	
									Training plan to encompass project and change management and HTA approach	X			Preventative		
									Development of procurement plan to deliver the DDAT Strategy	X			Preventative		
									SROs identified for Programme and individual projects	X			Preventative		
									Schedule a regular programme of staff engagement events	X			Preventative		
									Establish an external stakeholder communications and engagement plan	X			Preventative		
									Recruitment of new Authority Member(s) with digital and organisational change experience		X		Monitoring		
									Programme to become a focus for appropriate internal audit			X	Monitoring/ Detective		
									Appointment of external critical friend to counter potential optimism bias			X	Preventative		

HTA Board Report

Delivery – Quarter three 2019/20

Date	6 February 2019	**Paper Reference**	HTA (02/20)
Agenda Item	7	**Author**	Nicolette Harrison
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Strategic objectives (Delivery)	a) 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; b) Deliver effective regulation of living donation; c) Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit; d) 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; e) 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; f) Maintain our strategic relationships with other regulators operating in the health sector.		
Relevant key performance indicators (KPIs) (marked as red, amber, green, black or blue)	1. 180 site visits to take place during the business year across all sectors (year-to-date) 2. Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented (reported monthly) 3. 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly) 4. 100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days (average reported monthly) 5. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)		
Related Strategic Risks (marked as red, amber or green)	1 Failure to regulate appropriately (Objectives A-C & E) 2 Failure to manage an incident (All objectives) 3 Failure to manage expectations of regulation (Objective D) 4 Failure to utilise our capabilities effectively (Objectives A-D) **(see paper 1a/20 for detailed information)**		

Purpose of Report

1. To provide the HTA Board with standardised information on the delivery activities of the HTA and to highlight trends and any issues which require consideration by Members.

2. It is provided as a source of assurance on the delivery activities of the HTA each quarter and including statistics and background information in the Supplementary Data Annex HTA (2a/19).

Decision-making to date

3. This report was approved by the CEO on 29 January 2020.

Action required

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

Director's summary

5. During quarter three, we have maintained strong progress on delivering our core planned regulatory activity (such as licensing and inspections) whilst also making good progress in our technical / policy projects (such as the HA Risk work) and on important demand-led reactive activities, such as investigations and urgent approval requests, one of which has resulted in a police referral.

6. Better use of dashboards (referred to in the previous Delivery Report) has continued to help us focus our management of shortfalls and incidents, with significant progress seen in closing Human Application incident reports. More dashboards have been developed and will be brought into use over quarter four. The new inspection report templates were fully introduced in quarter three, new style bringing a much clearer focus on inspection findings. We have also continued to develop our relationship with other regulators, with better targeted information sharing with the Care Quality Commission (CQC) and some engagement with other non-health regulators, such as the Competition and Markets Authority (CMA).

Site Visits and Inspection Outcomes

Objective	Indicator	Activity	Performance Indicator	Q3 RAG rating
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.	KPI:1	Undertake a risk based inspection / audit programme	180 site visits to take place during the business year across all sectors (year-to-date)	Green

7. Site visits are on target, with 22 routine site visit inspections in the quarter plus two *Licence Application Assessment Visits (LAAVs).* LAAV numbers vary but we expect to do more in quarter four given the continuing steady inflow of new licence applications.

8. We approved five licence applications in the quarter and refused one, refusal of a licence being a relatively rare occurrence. The research sector continue to account for most new licence applications but there was also one anatomy sector application, which is again an unusual occurrence.

Corrective and Preventative Actions Plans

Objective	Indicator	Activity	Performance Indicator	Q3 RAG rating
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.	KPI:2	Take appropriate action for all regulatory non-compliances	100% of Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented (reported monthly)	

9. Delay by establishments was largely responsible for the CAPA key performance indicator not being met in two months of quarter three. This KPI is not rag-rated, as it reflects both HTA and establishment activity. We are expecting to review this Key Performance for next year to try to better distinguish those two aspects.

Sector Updates

<u>Anatomy</u>

10. No routine inspections were undertaken in quarter three and there was an expected level of background regulatory activity. One new licence application was received (see paragraph 8).

Post Mortem

11. The number of licensed establishments in the PM sector has not changed significantly in quarter three. One PM sector satellite licence was revoked in this quarter. A licence application was refused following a Licence Application Assessment Visit and a Regulatory Decision Making meeting.

12. We undertook six routine site visit inspections of PM sector establishments in quarter three. The number and types of shortfalls identified were consistent with previous quarters. Many of these shortfalls related to governance procedures, suitability of premises, facilities and equipment, and procedures for traceability of bodies and tissue. We are reviewing the guidance for the PM sector standards to provide additional guidance to establishments on how these standards can be met (see paragraph 16).

13. In quarter three, an investigation was commenced after the HTA received an allegation about mortuary security and release procedures at a licensed establishment. The investigation is ongoing.

14. A total of 60 HTA Reportable Incidents (HTARIs) were reported to the HTA in quarter three. This compares with 59 cases reported in quarter two and 44 cases reported in quarter one. The total number of cases determined to be HTARIs remains broadly similar on a year-by-year basis. In quarter three, 22 HTARI cases were closed that were determined to be incidents. We note the number of incidents of misidentification of bodies has decreased (particularly for incidents of viewing of the wrong body). We continue to provide guidance on strengthening identification procedures, through inspections, enquiries, HTARIs and advice on our website. For further information, please refer to table seven of the Supplementary Data Annex document. Three HTARI cases were referred to the CQC during this quarter.

15. In the December edition of the professional newsletter, we re-issued guidance on mortuary storage capacity and contingency arrangements relating to winter-pressures.

16. The guidance for the PM sector licensing standards is under review. This review is being informed by inspection findings, incidents and enquiries in the Post Mortem sector. We aim to publish the updated guidance by April 2020.

Public Display

17. We undertook one routine site visit inspection of a Public Display sector establishment in quarter three. There are no particular trends of non-compliance to note.

Research

18. Despite three research sector establishments opting to revoke their licences during quarter three, the number of licensed establishments in the research sector continued its long-term growth trend, with four new applications received. Although we undertake relatively fewer routine inspections in this lower risk sector, our Regulation Managers are frequently visiting sites as part of the process for assessing new licence applications.

19. We undertook three routine site visit inspections of research sector establishments during quarter three, with no notable trends in non-compliance to report; only one minor shortfall was identified. The two investigations outlined in the Delivery Report for quarter two continued during quarter three.

20. As in quarter two, we continued significant collaboration with the Health Research Authority (HRA), jointly launching two e-learning modules on research tissue banks (RTBs). We worked with the HRA's communications team to deliver a cross-channel campaign to raise awareness of the new modules.

Human Application

21. The number of licensed establishments in the HA sector has not changed significantly in quarter three. A total of 12 routine site visit inspections were conducted during this period. The number and types of shortfalls identified were consistent with previous quarters. In quarter four, the HTA plans to issue further guidance to the sector regarding the requirements for SAEARs reporting and risk assessments in an attempt to increase compliance with related licensing standards.

22. In quarter three, the HTA took the decision to make a police referral in relation to the carrying out of licensable activities by an unlicensed establishment. The initial referral has been made.

23. In quarter three, a total of 65 HA SAEARs were reported to the HTA (*cf.* approximately 80 were reported in each of the three previous quarters). As in previous quarters, a significant number of reported SAEARs related to potential sample contamination. The HTA is currently considering options to facilitate shared learning from such cases, and is reviewing its practices for how these types of SAEARs are managed to ensure effective use of resources. During quarter three, the HTA prioritised closure of SAEARs and trialled site visits as a way of closing clusters of SAEARs. As a result, 192 HA SAEARs were closed in quarter three (*cf.* 50 in the preceding quarter). For further information, please refer to table 8 in the Supplementary Data Annex document and Annex B, Closed Incidents.

24. In quarter three, the HTA worked with the MHRA to provide information to a journalist on the regulation of stem cell therapies.

Organ Donation and Transplantation

25. During quarter two, we became aware that removal of bone marrow from two donors had proceeded without HTA approval. An investigation led by the Head of Regulation, Organ Donation and Transplantation, commenced in quarter two and continued in quarter three, including a meeting with establishment staff.

26. Following the investigation, a decision was made by the SMT not to refer the case to the police. This was because the SMT were assured by the findings of the meeting with establishment staff that the matter had been taken very seriously, and a number of corrective and preventative actions had been implemented.

27. In quarter three a total of 32 ODT SAEARs were reported to the HTA, compared with 19 during the previous quarter. Forty-two ODT SAEARs were closed in quarter three. We continue to monitor the increase in ODT SAEARs closely and this remains a standing agenda item at quarterly meetings held with NHSBT. For further statistics please refer to table nine in the Supplementary Data Annex document.

28. We have continued to work closely with NHSBT colleagues during the revision of Code of Practice F following consultation, to ensure that changes can be implemented from a practical perspective.

Living Donation - Solid Organs

Objective	Indicator	Activity	Performance Indicator	Q3 RAG rating
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.	KPI:3	Make appropriately evidenced decisions to agreed quality standards	100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly)	Green
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.	KPI:4	Make appropriately evidenced decisions within agreed timeframes	100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days (average reported monthly)	Green

29. In quarter three, a total of 363 kidney and liver cases were considered for HTA approval. There was a 21% increase in the total number of cases approved in quarter three compared with quarter two, with a 12% and 43% increase in the number of cases approved by the Living Donation Assessment Team (LDAT) and Panel respectively. Table 4 in the supplementary information document provides further information on the number of cases considered by the LDAT compared to the number considered by Panel.

30. In quarter three, the LDAT approved 240 cases (directed and directed altruistic). 123 cases (paired/pooled and non-directed altruistic) were considered and approved by Panel. Tables 5a and 5b in the Supplementary Data Annex document provide a further breakdown on each case type approved by the LDAT and Panel.

31. In quarter three, the HTA considered one emergency living donation case for approval, compared to none in the previous quarter.

32. In quarter three, the LDAT considered 15 bone marrow and PBSC cases for HTA approval from donors lacking competence to consent, compared with 19 cases in the previous quarter. For further information please refer to table six in the Supplementary Data Annex document.

33. A Living Donation News bulletin was also circulated in November, as well as a blog post from an Independent Assessor (see paragraph 45 below).

Communications

Objective	Indicator	Activity	Performance Indicator	Q3 RAG rating
Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;	KPI:5	Respond to enquiries in a timely way	At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)	Green

<u>General enquiries</u>

34. During quarter three, the HTA recorded 854 general enquiries, compared with 1,012 in the previous quarter. The enquiries included:

    a. 460 from members of the public about body donation. This compares to 543 in the previous quarter.
    b. 394 general enquiries from public and professional stakeholders.

35. 97% of general enquiries were answered within 10 days in quarter three, compared to 93% in the previous quarter. Due to process issues, where through human error a number of cases were not closed within 10 days, despite being answered, the percentage of cases recorded as answered within the target is tracking lower than the actual performance.

Social media

36. The HTA's busiest social media channel in quarter three, as in previous quarters, was Twitter. However, as Table 10 in the data annex shows, impressions and engagements on Twitter, as well as reach and engagements on Facebook, were noticeably lower than in previous quarters; this reflects the reduced level of activity from both the HTA and other social media users over the Christmas and New Year period.

37. In quarter three, the HTA's Twitter account continued to grow, and had 2,376 followers, compared to 2,306 in the previous quarter. Our engagement rate was 1.0% compared to the previous quarter, which was 1.3%.

38. On average, HTA tweets were seen by 933 people per day, compared to the previous quarter where 1,098 people per day saw HTA tweets. Our impression rate this quarter was 12 impressions per tweet. This has increased from 11 impressions per tweet in the previous quarter.

39. There were 937 Facebook 'likes' on the HTA page, up compared to the last quarter.

40. The HTA had 738 followers for its LinkedIn company page, up compared to the previous quarter.

41. The HTA YouTube channel received 452 views, up compared to the previous quarter.

Digital communications and publications

42. The highest viewed pages were:
    a. Donating your body
    b. Medical school finder
    c. Homepage
    d. Codes of practice
    e. HT Act 2004

43. In October, visits to the body donation page on our website spiked to 3,000 (which is approximately three times the usual daily hit rate) following an item on BBC Breakfast News; 21% of all website traffic was to the body donation page (the average for the previous month was 9%). This also saw a spike of enquiries on body donation on the same day, with almost half the average monthly number of body donation enquiries coming in on one day.

44. For further information, please refer to table 12 in the Supplementary Data Annex document.

45. The HTA Blogs were viewed 421 times in quarter three. The most popular blog was 'Cheese sandwiches and kidneys' by Sue Taylor who is an IA. https://www.hta.gov.uk/blog/cheese-sandwiches-and-kidneys-role-independent-assessor

46. We will continue to review and monitor engagement with the blog to ensure it is of interest and value to our stakeholders.

Other stakeholder engagement

47. The HTA sent out a professional newsletter in December (open rate 30%) and a living donation newsletter in November (open rate 26%). The HTA public newsletter was sent out in October (open rate 32%).

48. The government average for open rates sits at 24%.

Board Supplementary Data Annex document
Delivery – Quarter three 2019/2020

Date	6 February 2020	**Paper Reference**	HTA (02a/20)
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Purpose of Report

1. This report sets out the data that should be referred to alongside the Delivery Report (paper reference, 02/20) and List of Closed Incidents, Annex B (paper reference, 02b/20).

Site visits and Inspection Outcomes

2. Table 1 shows the number of site visits, including licence application assessment visits that took place in quarter three compared to preceding quarters.

Table 1: Site visits (including licence application assessment visits (LAAVs))

Type of site visit	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Routine inspection	22	22	40	39	157	150	136
LAAV – new application	2	6	4	1	9	11	18
LAAV – variation	0	0	0	0	2	0	1
Satellite site inspection	9	9	20	11	49	66	46
CAPA follow up	0	0	4	1	6	5	1
Non-routine inspection	0	0	0	0	0	4	1
Total sites visited	**33**	**37**	**68**	**52**	**223**	**236**	**203**

3. Due to the time taken to finalise inspection reports, inspection findings are reported in quarterly arrears and cumulatively as year to date*. Tables 2a) below shows the numbers of shortfalls identified during routine inspections carried out during quarter two. Table 2b) shows the total number of shortfalls identified from all routine inspections carried out during quarters one and two and partial figures for quarter three.

Table 2a): Quarter 2: July – September 2019

Sector	Inspections	Minor	Major	Major cumulative	Critical	Critical cumulative
Anatomy	1	3	0	0	0	0
Post Mortem	4	35	34	0	0	0
Public Display	2	4	0	0	0	0
Research	2	25	9	0	0	0
Human Application	12	44	3	2	0	0
Organ Donation and Transplantation	1	0	0	0	0	0

Table 2b): *Year to Date: 2019/20

Sector	Inspections	Minor	Major	Major cumulative	Critical	Critical cumulative
Anatomy	2	3	0	0	0	0
Post Mortem	20	148	93	1	0	0
Public Display	4	10	0	0	0	0
Research	10	66	16	0	0	0
Human Application	46	170	6	3	0	0
Organ Donation and Transplantation	2	0	0	0	0	0

*Year to date includes total figures from quarters one and two and shortfalls identified for inspections in quarter three where the final report was issued before 10 January 2020.

Regulatory Activity

4. Table 3 below shows the regulatory activity that took place during quarter three.

Table 3: Regulatory activity

Sector	Investigations	Police Referrals Considered by SMT	Legal notices	RDMs	Revocations	Other*
Anatomy	-	-	-	-	-	-
Post Mortem	1	-	-	1	1 (satellite)	3*
Public Display	-	-	-	-	-	-
Research	2	-	-	1	4 (3 main, 1 satellite)	-
Human Application	2	2 (1 referred to police, 1 not)	-	4	3 (1 main, 2 satellite)	-
Organ Donation and Transplantation	-	1	-	-	-	-

* Three cases were referred to the CQC.

Living Donation

5. Table 4 below shows the total number of kidney and liver cases approved by the LDAT and Panel during quarter three. The total from preceding quarters is also shown below. The total number of cases approved includes those considered using the emergency out of hour's process.

Table 4: Total number of living donation cases approved

Quarter	TOTALS		
	Number of cases considered	Approvals by the Living Donation Assessment Team	Approvals by Authority panels
Q3 19/20	363*	240	123
Q2 19/20	300	214	86
Q1 19/20	289*	208	81
Q4 18/19	294*	213	81
19/20 Total Year To Date	**952**	**662**	**290**
18/19 Total Year	**1228****	**906****	**322**

* includes one case considered using the emergency out-of-hours process.
**includes one small bowel case.

6. Table 5a) below shows the number of kidney cases approved by LDAT and Panel and Table 5b) below shows the number of liver cases approved by LDAT and Panel.

5a): Kidney

Q3	LDAT	Panel
Directed	228	0
Directed Altruistic	3	0
Non Directed Altruistic	0	45
Paired/Pooled	0	75

5b): Liver

Q3	LDAT	Panel
Directed	9	0
Directed Altruistic	0	0
Non Directed Altruistic	0	3

7. Table 6 below shows the total number of bone marrow and PBSC cases approved (donors are children lacking competence to consent) in quarter three compared to preceding quarters.

Table 6: Total number of bone marrow and PBSC cases approved

	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2019/20 Total Year To Date	2018/19 Total Year
Approvals	15	19	15	24	49	71

Incidents

HTA Reportable Incidents (HTARIs)

8. In 2018/19, mortuaries licensed by the HTA admitted around 317,500 bodies, and performed over 90,000 post-mortem examinations. In this context, the number of reported HTARIs is very low.

9. The table below describes the number of HTARIs that were reported in each period. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents. Details of HTARIs that have been closed can be found in Annex B (02b/20) and moving forward will be published online as part of the HTA's publication scheme.

10. Table 7 below shows the number of reported HTARIs in quarter three compared to preceding quarters.

Table 7: HTARIs Reported during quarter three in the Post Mortem sector

	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Number of reported HTARIs	60	59	44	64	205	230	160

Human Application SAEARs

11. Given the nature of regulated activities carried out in the human application sector, it is difficult to calculate a total number of activities to establish a denominator to compare with numbers of events and reactions.

12. The table below describes the number of SAEARs that were reported in each period. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR. Details of SAEARs that have been closed can be found Annex B (02b/20) and moving forward will be published online as part of the HTA's publication scheme.

13. Table 8 below shows the number of reported SAEARs in quarter three compared to preceding quarters.

Table 8: Reported SAEARs in the human application sector

	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Number of reported SAEs	61	74	73	67	279	157	83
Number of reported SARs	4	9	7	13	44	27	24
Total	**65**	**83**	**80**	**80**	**323**	**184**	**107**

Organ Donation and Transplantation SAEARs

14. During 2018/19, a total of 5090 organ transplants, from 1574 deceased and 1051 living donors, were carried out in the UK.

15. The table below describes the number of ODT SAEARs that were reported in each period. This also includes any incidents that were, on investigation, found not to fit the criteria of an ODT SAEAR. Details of ODT SAEARs that have been closed can be found in Annex B (02b/20) and moving forward will be published online as part of the HTA's publication scheme.

16. Table 9 below shows the number of reported SAEARs in quarter three compared to preceding quarters.

Table 9: Reported SAEARs in the Organ Donation and Transplantation sector

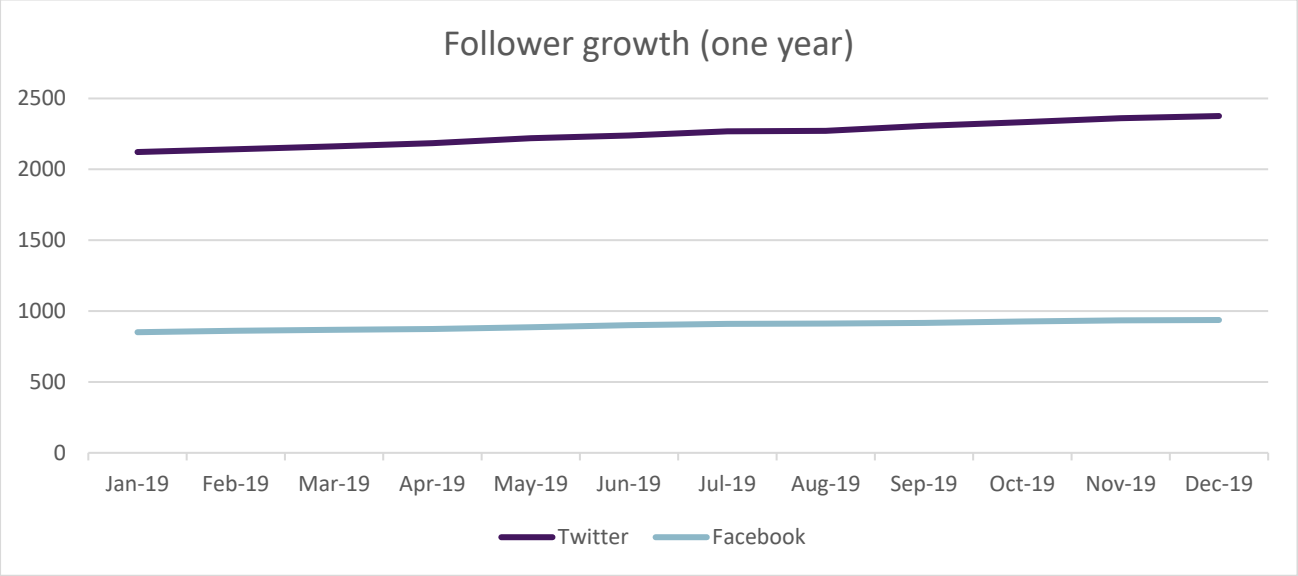
	Q3 2019/20	**Q2 2019/20**	**Q1 2019/20**	**Q4 2018/19**	**2018/19 Total Year**	**2017/18 Total Year**	**2016/17 Total Year**
Number of reported ODT SAEs	24	12	19	12	33	22	38
Number of reported ODT SARs	8	7	12	8	29	15	26
Total	**32**	**19**	**31**	**20**	**62**	**37**	**64**

Communications

Social Media audience, engagement and key metrics

17. Figure 1 shows how many people follow the HTA using Facebook and Twitter.

Figure 1: Changes in social media followers over one year



18. Table 10 below details the number of users our posts have reached (Impressions) and how many people have clicked on the content (Engagements).

Table 10: Engagement and key metrics for Twitter and Facebook

Twitter performance	Impressions	Engagements	Number of posts
Q3 2019/20	84,900	825	69
Q2 2019/20	101,100	1039	99
Q1 2019/20	139,800	1031	98
Q4 2018/19	63,100	474	55

Facebook performance	Reach	Engagements	Number of posts
Q3 2019/20	3,391	338	19
Q2 2019/20	6,995	568	27
Q1 2019/20	13,662	1,555	36
Q4 2018/19	7,931	465	49

19. Top tweets by impressions

- Announcing the start of the annual conference https://twitter.com/HTA_UK/status/1192011305567305729
- Announcing the live stream of the annual conference https://twitter.com/HTA_UK/status/1190256010528804865
- Congratulating Charmaine Griffiths becoming CEO of BHF https://twitter.com/HTA_UK/status/1194568334727094272

20. Top Facebook posts by reach

- BBC Breakfast piece on body donation https://www.facebook.com/HumanTissueAuthority/photos/a.572290766194389/2502822646474515/?type=3&theater
- Information on brain donation https://www.facebook.com/HumanTissueAuthority/photos/a.572290766194389/2500626686694111/?type=3&theater
- Information on how we regulate living organ donation https://www.facebook.com/HumanTissueAuthority/photos/a.572290766194389/2611612675595511/?type=3&theater

Website Performance and Reach

21. Table 11 below details the number of unique individual users who have visited the HTA website per quarter, and how many pages were viewed during this period.

Table 11: Website performance

	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year
Users	62,972	55,457	51,388	57,196	202,222
Page views	263,430	243,017	228,891	240,030	872,405

22. Table 12 below details the top five most visited pages on the HTA website.

Table 12: Top five most visited pages on the HTA website

Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19
Donating your body 32,292	Donating your body 23,578	Donating your body 20,307	Donating your body 24,308
Medical schools 17,577	Homepage 17,711	Homepage 16,320	Homepage 16,603
Homepage 17,293	Medical schools 12,731	Medical schools 10,862	Medical schools 12,659
Codes of practice 7,258	Codes of practice 6,633	Codes of practice 7,223	Codes of practice 7,938
HT Act 2004 7,151	Website search (any) 5,736	Website search (any) 5,795	HT Act 2004 6,176

23. Table 13 below shows how people find their way to the HTA website.

Table 13: Acquisition (how people arrive on our website)

	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year
Search engine	62.4%	60.3%	60.2%	61.3%	61.6%
Untracked	21.1%	21.9%	23.7%	24.2%	23.1%
Link on another website	13.4%	11.7%	12.6%	13.0%	13.9%
Social media	1.4%	4.4%	2.2%	1.1%	1.2%
Email	1.7%	1.7%	1.4%	0.4%	0.2%

24. Table 14 below details how many online enquiries were submitted via the website in quarter three compared to preceding quarters.

Table 14: Online enquiries

	Q3 2019/20	**Q2 2019/20**	**Q1 2019/20**	**Q4 2018/19**	**2018/19 Total Year**
Online enquiries	437	434	402	351	1029

Closed HTARIs and SAEARs in Q3 2019/20

Human Application SAEARs

Closed HA SAEARs

Type of Event or Reaction	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Event linked to Distribution	10	3	0	2	5	1	6
Event linked to End use	0	0	0	0	0	0	0
Event linked to Materials	1	0	1	0	0	1	2
Event linked to Preservation	0	0	0	0	0	0	4
Event linked to Processing	27	8	10	7	20	21	13
Event linked to Procurement	107	25	19	13	40	18	11
Event linked to Storage	5	5	4	2	4	10	10
Event linked to Testing	25	3	4	3	12	6	0
Event linked to Transportation	1	1	0	2	4	2	2
Event linked to Other process	11	5	4	2	5	8	4
Total – Events	**187**	**50**	**42**	**31**	**90**	**67**	**52**
Reaction in Donor	4	0	0	0	0	2	0
Reaction in Recipient	1	0	0	0	3	10	8
Total – Reactions	**5**	0	**0**	**0**	**3**	**12**	**8**
Total – Events and Reactions	**192**	**50**	**42**	**31**	**93**	**79**	**60**

Human Application – Serious Adverse Events closed in Q3 2019/20 – Details

Case Number	Process Event Linked To	Description of Event
CAS-41589-D8M8	Processing	Mislabelling of cryopreserved unit
CAS-50811-F6M2	Distribution	Incorrect tissue received
CAS-43923-N6C9	Storage	Storage of unlicensed tissue beyond 48 hours.
CAS-44168-N8L8	Storage	Release of tissue without replicated serology results
CAS-46013-H2V6	Procurement	Potential disease transmission
CAS-49315-J6Z8	Procurement	Positive sterility result
CAS-40646-Y1P3	Distribution	Tissue and cells transported outside validated timeframe
CAS-45902-B1L5	Processing	Error in processing resulted in loss of stem cells
CAS-50292-T6F9	Processing	Human error resulted in additional procedure

CAS-50506-Z1C3	Procurement	Loss of unit during collection due to a technical issue.
CAS-52413-J2K5	Storage	Delay in full dose of cells being issued owing to incorrect data entry
CAS-46402-M7T6	Procurement	Loss of unit during collection due to a technical issue
CAS-48029-R6P3	Procurement	Additional collection required due to a technical issue
CAS-50609-N3K1	Materials	Damage to stem cell bag
CAS-50898-T5G5	Testing	Initial sterility check post-procurement was positive
CAS-44677-H6N5	Testing	Positive microbial result on allograft - most likely donor-derived
CAS-45072-R2F9	Processing	Loss of tissue due to equipment issues
CAS-45063-Y4C3	Other	Incorrect Cell Count (result from external Lab) resulted in unnecessary mobilisation.
CAS-49876-W4T0	Procurement	Positive sterility on procured stem cells
CAS-49977-Y6F1	Processing	Positive sterility on processed stem cells
CAS-47715-X0T8	Procurement	Loss of unit during collection due to a technical issue.
CAS-50227-P7Z8	Procurement	Positive microbiology test result on procured unit.
CAS-41095-D0Y2	Procurement	Positive sterility on procured stem cells
CAS-41215-X3M1	Procurement	Positive sterility on procured stem cells
CAS-42446-G6X9	Procurement	Positive sterility result
CAS-42876-S8T9	Processing	Positive sterility post processing
CAS-43313-H4C2	Procurement	Positive sterility on procured stem cells
CAS-43510-Y9Q1	Procurement	Positive sterility on procured stem cells
CAS-43578-M9N6	Testing	Positive sterility on procured stem cells
CAS-43706-Y3J9	Testing	Positive microbiology test result on procured unit.
CAS-43758-N6V0	Testing	Positive sterility on procured stem cells
CAS-43899-X9L3	Procurement	Positive microbiology test result on procured unit.
CAS-44011-B0R1	Testing	Positive microbiology test result on procured unit.
CAS-44016-X5C3	Procurement	Sterility check post procurement was positive.
CAS-44432-J3F5	Testing	Positive microbiology test result on procured unit.

CAS-44433-R7T3	Testing	Positive microbial test on procured unit.
CAS-44463-P5Z3	Testing	Positive sterility following procurement
CAS-44808-J7H9	Procurement	Positive sterility on procurement
CAS-44885-K4C5	Procurement	Positive microbiology test result on procured unit.
CAS-44918-N2G2	Procurement	Positive sterility on procured stem cells
CAS-45135-V7V1	Procurement	Positive microbiology test result on procured unit.
CAS-45273-S1Y8	Testing	Positive sterility result
CAS-45578-L3M4	Testing	Positive serology results not reported in time
CAS-45755-N4Y7	Testing	Positive sterility result
CAS-46056-T4D3	Distribution	Absence of temperature monitoring data
CAS-46292-B7F6	Testing	Loss of sterility test samples
CAS-46347-X7Q2	Testing	Positive sterility by transplant centre
CAS-46384-P2H3	Testing	Tissue and cells procured with incomplete serology
CAS-47254-C3Z2	Testing	Positive sterility on procured stem cells
CAS-47349-R9H1	Procurement	Positive microbiology test result on procured unit.
CAS-47930-P8K2	Testing	Positive sterility on procured stem cells
CAS-48054-S6W1	Processing	Sterility check post procurement was positive..
CAS-48157-F9S4	Distribution	Tissue transported outside the required temperature range
CAS-48775-Y5Q1	Other	Positive microbiology test result on procured unit.
CAS-48829-X5F8	Procurement	Positive microbiology test result on procured unit.
CAS-49132-L2T0	Procurement	Sterility check post procurement was positive.
CAS-50272-J4Q0	Procurement	Positive microbiology test result on procured unit.
CAS-50348-C4K6	Procurement	Positive microbiology test result on procured unit.
CAS-50753-P6Y3	Procurement	Positive microbiology test result on procured unit.
CAS-50886-L4K6	Processing	Sterility test by collection centre was positive
CAS-50888-M3X2	Procurement	Sterility test by collection centre was positive

CAS-50987-W0T0	Procurement	Positive sterility check on procured unit.
CAS-51252-D8D4	Procurement	Positive microbiology test result on procured unit.
CAS-51721-X6M8	Procurement	Positive sterility test result post-processing
CAS-51774-B9K0	Testing	Initial sterility check post-procurement was positive
CAS-51995-K9M7	Procurement	Positive microbiology test result on procured unit.
CAS-52063-J7Q1	Procurement	Positive microbiology test result on procured unit.
CAS-52399-M7K7	Procurement	Positive microbiology test result on procured unit.
CAS-40642-G0N1	Procurement	Positive microbiology test result on procured unit.
CAS-41965-G0Z0	Procurement	Positive microbiology test result on procured unit.
CAS-42034-P9Q6	Other	Inappropriate release of tissue outside of set criteria.
CAS-42105-L9D5	Other	Positive microbiology test result on procured unit.
CAS-43034-Q4F0	Procurement	Positive microbiology test result on procured unit.
CAS-43133-G4J2	Other	Positive microbiology test result on procured unit.
CAS-43533-P9F9	Processing	Positive microbiology test result on procured unit.
CAS-43534-N9F7	Procurement	Positive microbiology on procured stem cells
CAS-43698-J3Q0	Processing	Positive microbiology on processed stem cells
CAS-43750-S6D8	Procurement	Positive microbiology test result on procured unit.
CAS-44188-P2D9	Testing	Positive microbiology test result post processing.
CAS-44342-L5H4	Procurement	Temporary relocation of Licensed premises following a fire
CAS-44833-Y6Z1	Procurement	Positive microbiology test result on procured unit
CAS-45104-H7X0	Procurement	Omission in SOP resulted in unnecessary stem cell collection
CAS-45137-K5G1	Procurement	Positive microbiology test result on procured unit.
CAS-45199-K3J2	Procurement	Positive microbiology test result on procured unit
CAS-45240-M7Z5	Procurement	Positive microbiology test result post processing
CAS-45281-H7F7	Processing	Potential leaching of chemicals into units
CAS-45470-J2N2	Procurement	Positive microbiology test result on procured unit

CAS-45484-X1H1	Procurement	Positive microbiology test result post processing
CAS-45758-J9Y6	Other)	Positive microbiology test result on procured unit.
CAS-45760-Z3F9	Procurement	Positive microbiology test result on procured unit
CAS-46060-X3Z2	Procurement	Positive microbiology on procured stem cells
CAS-46074-Q0L6	Procurement	Positive microbiology on processed stem cells
CAS-46354-P7H4	Procurement	Positive microbiology in released unit
CAS-46518-N4G8	Processing	Loss of tissue following processing error.
CAS-46694-P9Y2	Procurement	Positive microbiology test result on procured unit
CAS-46704-Y2N2	Procurement	Positive microbiology test result on procured unit.
CAS-46957-H5T1	Procurement	Positive microbiology test result on procured unit.
CAS-47212-W0Y4	Procurement	Positive microbiology test result on procured unit
CAS-47757-F4N1	Procurement	Positive microbiology of procured stem cells
CAS-47759-X0Z7	Procurement	Positive microbiology result on procured unit
CAS-47937-H7K3	Procurement	Positive microbiology result
CAS-48568-P4P0	Distribution	Tissue damage post-release
CAS-48619-X6N2	Processing	Microbiology check post processing was positive.
CAS-48975-H2D9	Procurement	Microbiology check post procurement was positive.
CAS-49181-Q3N9	Procurement	Failure to procure a directed cord blood unit by procuring hospital.
CAS-49252-C4S7	Procurement	Positive microbiology test result post processing.
CAS-50059-G2W5	Testing	Positive microbiology test result on procured unit
CAS-50383-H5L0	Processing	Microbiology check post processing was positive
CAS-50686-T4F9	Procurement	Positive microbiology test result on procured unit
CAS-50740-S6W7	Processing	Microbiology check post processing was positive
CAS-50741-Y2V4	Processing	Microbiology check post processing was positive
CAS-50744-B1F5	Processing	Unsuitable tissue issued for end use
CAS-50745-D3K5	Processing	Unsuitable tissue issued for end use

CAS-51121-C3D1	Testing	Positive microbiology test result post processing.
CAS-51142-M5D0	Distribution	Unsuitable allograft released for end use
CAS-51332-G6F9	Procurement	Potential donor derived disease
CAS-51459-N3W5	Processing	Positive sterility test result post-processing
CAS-51529-T8D1	Procurement	Positive microbiology test result on procured unit.
CAS-51689-Z4F0	Procurement	Positive microbiology check on procured unit.
CAS-52095-R5Z9	Procurement	Positive microbiology test result on procured unit.
CAS-52403-Q5Q5	Procurement	Positive microbiology test result on procured unit.
CAS-50314-Y5J3	Procurement	Positive microbiology test result on procured unit
CAS-44967-M3K7	Other	Loss of small amount of cell wash
CAS-45346-Z6F3	Processing	Units not used due to presence of clots
CAS-49818-V1Y3	Procurement	Positive microbiology test result on procured unit
CAS-38621-P5H1	Procurement	Low cell dose may have contributed to failed engraftment
CAS-37377-Q6C1	Processing	Poor viability following cryopreservation
CAS-49592-G7C0	Storage	Loss of cells from damaged bag
CAS-43833-B3Q5	Procurement	Loss of some of stem cell unit during transfusion
CAS-46224-Q7X3	Storage	Possibility of disease transmission with stored cells
CAS-43668-H8V9	Procurement	Incorrect storage conditions resulted in disposal of tissue and cells
CAS-44515-C6F2	Other	Imported products did not meet the EU legislative requirements
CAS-45688-B1R4	Distribution	Equipment fault caused loss of temperature but cells not affected
CAS-49769-Q2P8	Procurement	Unlicensed procurement
CAS-50656-H1K9	Processing	Tissue discarded due to loss of traceability
CAS-51762-G3G1	Procurement	Tissue discarded due to communication error
CAS-38093-V2T3	Procurement	Unlicensed procurement
CAS-38569-G2D0	Other	Incorrect packaging resulted in loss of tissue
CAS-41640-G6Z8	Testing	Stem cells released without full processing sterility checks, with no impact on recipients

CAS-45139-R1Q0	Transportation	Small loss of stem cell that did not impact patient treatment, following a road traffic accident that is considered to have led to damage to one of the frozen stem cell bags
CAS-45790-J4G9	Distribution	Loss of traceability of tissue due to error in distribution
CAS-45903-L1W8	Testing	Mandatory serology testing not conducted within the required timeframe due to misunderstanding of advice received from HTA
CAS-49241-X4H0	Other	Sterility check procedure of culture results available only post-clinical use not followed fully, with no impact on patient
CAS-44351-G8C7	Processing	Inaccurate stem cell counts impacting the dose infused
CAS-48210-M4X0	Procurement	Donor derived disease transmission
CAS-47229-X5F8	Procurement	Positive microbiology test result on procured unit
CAS-48763-R7P0	Procurement	Donor derived microbial contamination
CAS-42859-D5S8	Procurement	Positive microbiology test result on procured unit.
CAS-43579-C3S2	Procurement	Sterility check post procurement was positive.
CAS-43754-B4H5	Procurement	Positive microbiology test result on procured unit.
CAS-44111-G9N7	Procurement	Sterility check post procurement was positive.
CAS-44115-Z7Z5	Procurement	Sterility check post procurement was positive.
CAS-44444-G4J2	Testing	False positive serology result
CAS-44549-W6W3	Procurement	Positive microbiology test result on procured unit.
CAS-45786-K9B1	Procurement	Positive microbiology test result on procured unit.
CAS-45817-J0S1	Procurement	Sterility check post procurement was positive.
CAS-46091-F8Z7	Processing	Sterility check post procurement was positive.
CAS-46852-K6G7	Procurement	Sterility check post procurement was positive.
CAS-47271-W6L3	Procurement	Positive microbiology test result on procured unit.
CAS-47321-T0D3	Procurement	Sterility check post procurement was positive.
CAS-47654-S9X3	Procurement	Sterility check post procurement was positive.
CAS-47657-P1D6	Procurement	Sterility check post procurement was positive.
CAS-47679-M5F5	Procurement	Sterility check post procurement was positive.
CAS-47938-K3P5	Procurement	Sterility check post procurement was positive.

CAS-48444-G3T2	Procurement	Sterility check post procurement was positive.
CAS-49136-F5P0	Procurement	Sterility check post procurement was positive.
CAS-49718-T9M4	Procurement	Sterility check post procurement was positive.
CAS-49772-R2R7	Procurement	Sterility check post procurement was positive.
CAS-49777-N5G0	Procurement	Sterility check post procurement was positive.
CAS-49821-W3Y9	Procurement	Sterility check post procurement was positive.
CAS-49992-B5B0	Procurement	Sterility check post procurement was positive.
CAS-53164-R1V4	Processing	Equipment failure resulted in loss of cells
CAS-42930-C0B7	Procurement	Positive sterility on procured stem cells
CAS-43117-Z5C8	Procurement	Positive sterility on procured stem cells
CAS-44001-T8Y3	Procurement	Positive sterility on procured stem cells
CAS-46558-H4K2	Procurement	Positive sterility on procured stem cells
CAS-48774-Z6B0	Procurement	Potential disease transmission
CAS-46297-Q7V6	Procurement	Positive serology result not communicated
CAS-50930-W6X2	Testing	Mandatory serology testing not conducted within the required timeframe.
CAS-48584-Q1H2	Procurement	Positive microbiology test result on procured unit
CAS-49924-F2L5	Distribution	Tissue transported outside the required temperature range
CAS-49546-R4Z2	Procurement	Serology tests not conducted within required time-frame
CAS-49591-D7B5	Procurement	Loss of cells from damaged bag
CAS-40305-Q9T4	Processing	Loss of unit through bag leakage
CAS-44327-N1G1	Other	Positive sterility result on procured unit
CAS-47188-M9T4	Distribution	Possible loss of traceability due to unlabelled starting material
CAS-47543-Y9S0	Processing	Sterility check post processing was positive.

Human Application – Serious Adverse Reactions closed in Q3 2019/20 – Details

Case Number	Donor or recipient affected	Description of Reaction
CAS-37101-L0R5	Recipient	Positive microbial result on allograft
CAS-45478-Z5M7	Donor	Donor reaction following stem cell donation
CAS-46439-T0L5	Donor	Reaction to medication
CAS-51320-X3Q0	Donor	Donor reaction
CAS-36377-G3M8	Donor	Patient infection post surgery, not attributable to implant.

Organ Donation and Transplantation SAEARs

Closed ODT SAEARs

Type of Event or Reaction	Q3 2019/20	Q2 2019/20	Q1 2019/20	Q4 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Events	29	17	10	9	20	29	28
Reaction in Donor	0	0	1	0	0	1	0
Reaction in Recipient	13	9	13	7	20	17	18
Total	**42**	**26**	**24**	**16**	**40**	**47**	**46**

Organ Donation and Transplantation – Serious Adverse Events closed in Q3 2019/20 – Details

Case Number	Brief description of incident
CAS-46762-T9B6	Probable donor derived infection
CAS-49180-C9T2	Damage to organ - not transplanted
CAS-49472-G5D3	Complications during retrieval process
CAS-49526-R3G8	Finding post transplant
CAS-49701-C1J1	Potential for donor derived disease
CAS-49704-M6R8	Potential for donor derived disease
CAS-50472-D5F5	Damage to organ - recipient impacted
CAS-50475-V8D9	Potential donor derived infection
CAS-50583-V2V5	Damage to organ - not transplanted
CAS-50864-R4Y9	Damage to organ - not transplanted
CAS-50951-L7N2	Damage to organ - not transplanted
CAS-51207-T6Y2	Damage to organ - recipient impacted
CAS-51243-H8M4	Damage to organ - not transplanted
CAS-51483-M1D5	Damage to organ - recipient impacted

CAS-51769-B7X7	Logistics - organ untransplantable
CAS-51904-Y1B7	Potential for donor derived disease
CAS-52092-R0S2	Probable donor transmitted infection
CAS-52094-Y3G9	Biopsy site bleed
CAS-52384-R2T3	Potential donor derived infection
CAS-52598-T3V0	Damage to organ - not transplanted
CAS-52601-N7D9	Potential for donor derived disease
CAS-52818-D2N8	Damage to organ - not transplanted
CAS-52828-D1C9	Damage to organ - not transplanted
CAS-52838-N3W0	Damage to organ - not transplanted
CAS-52839-M0Y4	Damage to organ - not transplanted
CAS-53176-H8S4	Damage to organ - not transplanted
CAS-53240-N8G7	Damage to organ
CAS-53390-Y0M3	Organ packing - not transplanted
CAS-53415-Z0Q9	Unexpected finding post transplant

Organ Donation and Transplantation – Serious Adverse Reactions closed in Q3 2019/20 – Details

Case Number	Donor or Recipient	Brief description of Reaction
CAS-46763-Q5H4	Recipient	Probable donor derived infection
CAS-47502-Y5Q7	Recipient	Damage to organ - recipient impacted
CAS-49464-P7B6	Recipient	Recipient impacted post transplant
CAS-50473-K9J5	Recipient	Damage to organ - recipient impacted
CAS-50478-Z7X9	Recipient	Potential donor derived infection

CAS-51208-Z8K1	Recipient	Damage to organ - recipient impacted
CAS-51484-S5K0	Recipient	Damage to organ - recipient impacted
CAS-51905-F7V2	Recipient	Potential for donor derived disease
CAS-52014-D7P6	Recipient	Prolonged retrieval - recipient impact
CAS-52093-Y6C5	Recipient	Probable donor transmitted infection
CAS-52096-H2W7	Recipient	Biopsy site bleed - recipient impacted
CAS-52344-B4C5	Recipient	Damage to organ - recipient impacted
CAS-52599-W9W3	Recipient	Potential for donor derived disease

Post Mortem HTA Reportable Incidents

Closed HTARIs

HTARI Classification	Q3 2019 /20	Q2 2019 /20	Q1 2019 /20	Q4 2018 /19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Accidental damage to a body	10	12	9	14	47	48	33
Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination, or during the repatriation or embalming process	0	0	0	0	0	0	0
Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	0	0	1	0	0	2	0
Loss, disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1	2	8	4	8	4	7
Disposal or retention of an organ or tissue against the express wishes of the family	2	2	0	1	1	5	0
Discovery of an organ or tissue following post-mortem examination and release of body	1	0	2	5	8	9	4
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	0	0	0	1	1	1	1
Loss of an organ	0	1	2	0	2	6	0
Major equipment failure	4	5	3	1	4	8	8
Post-mortem examination conducted was not in line with the consent given or the PM examination proceeded with inadequate consent	0	0	1	0	2	2	1
Post-mortem examination of the wrong body	0	1	0	0	4	3	2
Release of the wrong body	0	5	5	0	10	15	9
Removal of tissue from a body without authorisation or consent	0	0	0	0	6	1	2
Serious security breach	1	1	4	0	10	8	1
Viewing of the wrong body	0	1	1	0	5	9	9

HTARI Classification	Q3 2019 /20	Q2 2019 /20	Q1 2019 /20	Q4 2018 /19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given	0	0	0	0	0	0	0
Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	3	0	12	5	38	28	12
Total	**22**	**30**	**48**	**31**	**146**	**149**	**89**

Please note that some HTARI categories were revised slightly in May 2019.

Post Mortem HTA Reportable Incidents closed in Q3 2019/20 – Details

Case Number	Incident Classification	Brief summary of HTARI
CAS-48467-P6C2	Serious security breach	Security breach of mortuary processes.
CAS-50277-L7S2	Accidental damage to a body	Human error led to damage to a body whilst being transferred into the mortuary.
CAS-50347-J8Y9	Disposal or retention of an organ or tissue against the express wishes of the family	Human error led to loss of fetal tissue.
CAS-50648-F6V0	Accidental damage to a body	Accidental damage to a body during transfer to mortuary storage
CAS-50752-B9Z3	Major equipment failure	Equipment failure resulted in temporary transfer of bodies to alternative storage.
CAS-50832-F8V0	Accidental damage to a body	Procedural error for storage conditions led to damage to a body.
CAS-50927-V3V1	Accidental damage to a body	Human error led to accidental damage to a body whilst being transferred into the mortuary.
CAS-50970-J4P9	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-51022-M1Q7	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Examination of foetal remains was conducted without appropriate consent.
CAS-51058-T2Y1	Major equipment failure	Major equipment failure and procedural error led to damage to bodies in refrigerated storage.
CAS-51136-C3W9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to the short term release of a body from the mortuary without appropriate authorisation

CAS-51248-N6G6	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Complaint received for alleged theft of valuables.
CAS-51695-S8Q8	Loss, disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Procedural error led to disposal of a fetus by a means not in line with the family's wishes.
CAS-51742-J2H4	Accidental damage to a body	Procedural error led to accidental damage of a body
CAS-51917-B6X1	Major equipment failure	Equipment failure resulted in temporary transfer of bodies to alternative storage.
CAS-52032-S6Z7	Accidental damage to a body	Human error led to minor damage to a body during a post mortem examination
CAS-52118-S4L1	Accidental damage to a body	Human error led to minor damage to the body during a post-mortem examination.
CAS-52194-L7W8	Discovery of an organ or tissue following post-mortem examination and release of body	Failure to follow procedure led to discovery of tissue following release of a body.
CAS-52391-W9M4	Accidental damage to a body	Human error led to accidental damage to a body being placed into refrigerated storage.
CAS-52418-M7K6	Major equipment failure	Fridge/freezer failure resulted in transfer of bodies to another HTA licensed establishment
CAS-52571-K1W3	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-52841-J8P9	Disposal or retention of an organ or tissue against the express wishes of the family	Human error led to retention of tissue

HTA Board Report

Development – Quarter three 2019/20

Date	6 February 2020	**Paper Reference**	HTA (03/20)
Agenda Item	8	**Author**	Louise Dineley
Protective Marking	OFFICIAL	**Author Contact** Louise.dineley@hta.gov.uk	
Strategic objectives (Development)	a) Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target out resources effectively; b) Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk; c) 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; d) Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.		
Relevant KPIs (marked as red, amber, green, black or blue)	1. PROJECT: Implementation of improvements to target areas of risk in the HA sector. 2. PROGRAMME: Develop and implement a series of business cases for projects which will form the HTA's organisational development programme. 3. PROJECT: Develop a revised Code of Practice to provide practical guidance on the implementation of deemed consent for organ donation.		
Related Strategic Risks (marked as red, amber or green)	1 Failure to regulate appropriately 2 Failure to manage an incident 4 Failure to utilise our capabilities effectively **(see paper (01a/20) for detailed information)**		

Purpose of paper

1. To provide the HTA Board with standardised information on the development activities of the HTA and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the development activities of the HTA.

Decision-making to date

3. This report was approved by the CEO on 27 January 2020.

Action required

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

Director's summary

5. Over the last quarter good progress has been made in setting the foundation to progress the strategic objectives previously agreed, in spite of resource constraints. The pace of change in particular the embedding and adoption of programme management rigour has been affected by the delay in appointing a substantive Project Manager. Similarly, the ambition set out in the DDAT Strategy last year was predicated on a significant investment. However, the absence of this investment has led to a reconsideration of how we implement. This revision has coincided with my first quarter as Director and a renewed perspective which combined with a positive discussion at the Strategy Away Day with Members has confirmed priorities for 2020/21 and projects to progress and conclude in quarter four.

6. Projects commenced in quarter three and for completion in quarter four include:

    - Cloud migration and adoption of Office 365;
    - Independent review of the HTA's systems for the collection, collation and analysis of data and the processes for managing information;
    - Identification and progress towards an HTA intranet with functionality by the end of quarter four;
    - Focus on the use of intelligence to understand regulatory risk and sector specific risk;
    - Commission of a review of the requirements and business needs from an Electronic Document & Records Management System (EDRMS).

7. By the end of quarter four 2019/20 our aim will be to have strengthened our capacity and capabilities in the following areas:

    - Understanding the limitations our business systems and technology and targeting areas for improvement;
    - Use of data and information to identify and respond to regulatory risk in sectors;
    - Opportunities to integrate and align business systems to optimise interoperability and strengthen the effectiveness of user experience;
    - Internal communications and access to consistent and core messages via the intranet.

Project updates

Core 2019/20 projects

8. The three projects below were considered core during 2019/20.

PROJECT: Implementation of improvements to target areas of risk in the Human Application (HA) sector

9. During quarter three, the HTA continued to develop its procedures and documentation relating to inspections and the review of preparation process dossiers.

10. At a project team meeting in December, it was agreed that a number of pieces of work that were originally planned to be undertaken as part of this project would be completed as part of new, cross-sector projects currently being scoped by the Head of Development. These include, for example, the work on the development of a formal risk-based model for inspections. It was also agreed that the review of licensing standards would be deferred.

11. The majority of the project's remaining actions are due for completion by the end of quarter four. Work is currently underway to finalise amendments to PPD- and inspection-related procedural documents and an SMT paper is being drafted on 'deemed authorised' preparation processes.

PROJECT: Develop a revised Code of Practice to provide practical guidance on the implementation of deemed consent for organ donation

12. During quarter three, the HTA revised Code of Practice F to reflect comments and feedback received during the consultation. Specifically, a new introductory section has been added, and a section which clarifies new legal terms introduced by the Organ Donation (Deemed Consent) Act 2019. The interpretation and general guidance section has been extensively revised to explain all terms of substance that appear throughout the Code of Practice.

13. The sections on role of the family in an organ and tissue donation scenario and the faith and belief sections have been extensively revised following consultation feedback. Further information on the HTA's response can be found in the Outline of the Consultation Response paper, agenda item 13 (HTA 06/20).

14. The Code of Practice was circulated to Members for final sign off. The Code has been shared with colleagues at DHSC to enable the Ministerial clearance process to begin.

PROGRAMME: Develop and implement a series of business cases for projects which will form the HTA Development Programme.

HTA Office Relocation

15. During the course of quarter three, 24 members of staff joined tours of the new office building and the floor the HTA will occupy. The last tours took place in December and in January we will seek feedback from those staff who visited the new office.

16. Also in this period the cross-organisation working groups were formed and are each in the process of formalising their terms of reference.

Electronic Document and Record Management System (EDRMS)

17. In quarter three we have developed an outline specification of our EDRMS requirements. We have committed to procuring the services of an external consultancy in quarter four to fully develop those requirements and recommend the best fit solution.

Migration to Cloud Services

18. In this quarter we began work on the HTA migration to cloud services. This programme of activity will include projects to boost productivity, increase security and compliance and improve the end-user computing experience, as well as to consolidate some existing HTA services onto a cloud platform and deliver benefits including:

    - Increased mobility with secure access to files and email on any internet connected device and the ability to work offline and automatically re-synchronise when internet connections are unstable or not available;
    - Real-time collaboration and co-authoring of Word, Excel and PowerPoint documents with all collaborators able to see edits and additions as they happen;
    - Improved communications with the latest version of Microsoft Exchange (the email server), Microsoft Teams which includes all of the latest functionality of Skype for Business;
    - Increased productivity with personal productivity insights enabling staff to increase their collaboration time, improve meeting efficiency, eliminate distractions and ultimately reduce the time spent working resulting in an improved work-life balance.

Review of the HTA's data and intelligence systems

19. In quarter three we commissioned a review of the internal systems and processes for the collection, collation and management of data and information related regulatory activity. This review is due to report in mid-February with the findings and recommendations being used to inform the next steps of how the HTA uses and can develop its capabilities in the use of information.

Internet Redevelopment and Accessibility Project

20. In November 2021, the platform the HTA website is built on (Drupal 7) will officially reach its "end of life" phase; this means that automated testing will be shut down, and no more updates will be provided by the Drupal Security Team.

21. Additionally, and more urgently, new web accessibility standards for public sector websites require existing websites to be compliant by 23 September 2020.

22. In August an options paper with an attendant business case was tabled at the Senior Management Team Meeting, and a project to redevelop the HTA website was signed off, this will include:

    i. moving the HTA website onto a newer platform;

    ii. ensuring the HTA website adheres to the incoming accessibility requirements (pending an accessibility audit from an external independent company); and,

    iii. improvements to the user journey on the site through improved architecture, design, search functionality, and updated and improved content management.

23. An initial pre-stage of this project has already begun, and will run throughout quarter four to establish user requirements, which will provide the evidence-base for the project's initiation in quarter one 2020/21.

24. This project will run across the 2020/21 business year, and involve a large degree of external stakeholder engagement.

Additional 2019/20 projects

25. In quarter three of 2019/20, the following projects were considered to be of importance.

<u>Independent Assessor Sustainability Work</u>

26. Good progress continues to be made with the project and it is on target for completion as planned by the end of the 2019/20 business year.

27. Further online refresher training covering equality and diversity and the General Data Protection Regulation (GDPR) / data protection has been written and approved. Case study examples covering each donation case category have been written and recorded and will be uploaded to the portal shortly.

28. A Code of Conduct has been issued to all Independent Assessors (IAs) and each IA has been asked to read, sign and return a copy to the HTA.

Annual Compliance updates

29. In quarter three, we completed our latest collection of compliance updates. They are an important form of non-inspection regulatory oversight and baseline risk-profiling, enabling whole-sector inspection prioritisation to be assessed every two years.

30. The compliance update information will be used to improve our licensing records, prioritise inspections and inform our approach in each sector. Following our analysis of the data, we will consider how best to reflect any emerging trends or useful learning points. We have also held a post-project review and will use the feedback to inform the planning for the next round of updates, in 2021.

EU Exit

31. At the beginning of quarter three, we implemented our no deal plans in full. This involved redeployment of four Regulation Managers into office-based duties so that they were available to respond to EU Exit related enquiries and to provide an immediate response to any issues that arose. Daily situation reports for relevant members of the HTA Management Group were instigated.

32. This operational delivery phase lasted until the extension of Article 50 on 28 October 2019, at which point we stepped-down our no deal plans. Since then, we have begun to refocus on future planning and have carried out a lessons-learned review. We will take the findings from this forward into future EU Exit work and intend to extrapolate them more widely into incident response planning.

33. During this quarter, we were able to allocate a dedicated Project Manager to EU Exit. This resource was recruited on a temporary basis and greatly improved the co-ordination of our stand-up phase, as well as allowing us to better deploy key staff at Head level.

Developing learning resources for licensed establishments

34. In quarter three, the Licensed Establishment Engagement Programme (LEEP) revised its key priorities and milestones document, which sets out tasks that the group will focus on in the future. These include various projects aimed at improving learning resources for establishments, for example:

    a. Developing a series of webinars aimed at licensed establishments;
    b. Improving licensing information on the HTA website, including developing an interactive tool that make our requirements clear; and

c. Producing an updated handbook for DIs, CLHs and PDs that sets out their roles and responsibilities under each piece of HTA legislation.

35. The HTA held its annual conference in November. One of the table discussion topics focussed on how the HTA communicates with licensed establishments. In quarter three, the table discussion feedback was collated and analysed along with the online test data. This data will be shared and discussed with the internal HTA Management Group in quarter four, along with a proof of concept and a draft syllabus for webinars, to be considered in the wider work and resource planning activity.

Development of HTA Intranet

36. In quarter three, a decision was taken to explore the option of establishing an HTA intranet, using some of the remaining budget for 2019/20. Following some initial discussions around the possibilities, it was agreed that some user and administrator research would be conducted to arrive at the best possible options within the time frames available.

37. Three drop-in workshops were hosted with staff across the organisation, to capture user needs, and discuss how the intranet would best work for them.

38. In December, an options paper detailing potential intranet solutions was considered by the Senior Management Team. This paper outlined a selection of technical solutions for establishing an initial intranet build in quarter four, and included a “do nothing” option.

39. The agreed next steps from this discussion were to conduct further testing on two preferred solutions before a final decision could be made in quarter four in advance of any work being taken forward. In January 2020 a decision was made on a preferred option. Work is progressing to prepare for its implementation.

Development KPI narrative

Performance against 2019/20 KPIs

KPI 1 (HA risk project) and KPI 5 (Code of Practice F, Deemed Consent) remain amber during quarter three. Progress continues to be made with the implementation of the development programme and execution of individual projects. It is anticipated that this progress will be reflected in the rating at the end of quarter four, in the meantime this will remain as amber.

Projects scheduled in the next six months

Project	Brief description	Start date
Internet Redevelopment and accessibility project	Due to new accessibility requirements for public sector websites coming into force in November 2020, and the current version of software which the HTA website is built on coming to its “end of life” phase in 2021, we have committed resource to redeveloping the website. This will include moving to a new platform and carrying out changes and improvements to ensure the site is compliant with the new accessibility requirements.	January 2020
Regulatory risk and intelligence	Project to be scoped following report in mid-February. This project will aim to identify opportunities and priorities in the development of our systems and processes for the management of data and its use in the identification of regulatory risk.	February 2020
Intranet Development	Building on the capability and capacity developed in quarter four populate the HTA intranet.	April 2020

HTA Board Report

Deployment – Quarter three 2019/20

Date	6 February 2019	**Paper Reference**	HTA (04/20)
Agenda Item	9	**Authors**	Richard Sydee Allan Marriott-Smith
Protective Marking	OFFICIAL	**Author Contact** richard.sydee@hta.gov.uk allan.marriott-smith@hta.gov.uk	
Strategic objectives (Deployment)	a) Manage and develop our people in line with the HTA's People Strategy; b) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money; c) Provide a suitable working environment and effective business technology, with due regard for data protection and information security; d) Plan and prioritise our resources to carefully balance activity across the organisation.		
Relevant KPIs (marked as red, amber, green, black or blue)	1. Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly) 2. Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly) 3. Actual income versus budgeted income (reported monthly); Actual spend versus budgeted spend (reported monthly); Actual cash reserves versus required reserve of £1.8m (high risk if deficit is more than 10%) (reported monthly) 4. Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less DHSC Grant-in-Aid and devolved governments income) (reported quarterly); 5. Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly)		
Related Strategic Risks(marked as red, amber or green)	2 Failure to manage an incident 4 Failure to utilise our capabilities effectively 5 Insufficient, or ineffective management of financial resources **(see paper 01a/20 for detailed information)**		

Purpose of paper

1. To provide the HTA Board with standardised information on the deployment of HTA resources and to highlight any issues which require consideration by Members.

2. It is provided as a source of assurance on the deployment of HTA resources.

Decision-making to date

3. This report was approved by the CEO on 29 January 2020.

Action required

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

Directors' summary

5. From a people persepective, good progress has been made with developing policies associated with remote working and on preparing the ground for the introduction of remote working contracts in advance of the office move in November 2020.

6. There has been significant investment in training over the quarter, and this will continue for the remainder of the business year, to make good use of the additional funds available to year end.

7. Attraction of suitable candidates to vacant posts remains a challenge and poses potential difficulties for pressing ahead with the HTA Development Programme. Mitigations are being developed.

8. At the end of quarter three of the financial year the HTA was underspent against its planned budget by c£360k. This is primarily due to the resolution of a long standing dispute regarding VAT on the office accommodation at 151 Buckingham Palace Road.

9. Our income forecast is broadly balanced, the impact of further reorganisation and revocations in the Human Application (HA) sector has been offset by increased licence applications in the research sector.

10. Our full year forecast contains a number of additional activities, largely relating to digital transformation, that we are able to fund from the released VAT accrual. Overall, a small surplus of £100k remains although this does not take account of some planned expenditure that is still under consideration.

People

Training

11. The Wellbeing Training Programme was designed specifically to address issues identified in the HTA Stress Survey and Audit. Eighty seven individual training opportunities were accessed between September and December 2019. The programme has offered the following opportunities: Mental Health First Aiders; Mental Health Awareness; Change Management; Assertiveness; Resilience; and Talking to Vulnerable People. Spare capacity was offered to and filled by other Arm's Length Bodies (ALBs). Mindfulness training was offered in January 2020 with an additional 21 individual spaces booked.

12. An overall combined satisfaction score for these courses for September to December was 50%. The feedback highlighted a need for the provision of more tools to take away and greater participant interaction. All feedback will be taken into account for the design of future courses.

13. The general 2019/2020 training programme continues. Opportunities include:

    - Following a Human Tissue legislation training needs review, HTA-wide training has been arranged for the 26th March. This will be facilitated by Field Fisher Solicitors.
    - One session of Training in Report Writing was delivered in December to half the Regulation Managers with a second session held on 30 January for all remaining Regulation Managers.
    - Public speaking training was scheduled for 17 January to support Regulation Managers specifically but also the wider organisation as needed.
    - The Lunch and Learn programme is embedding well with a variety of topics already covered from 'Simple Excel reporting' to 'Working in Serria Leone with the Ebola outbreak' to 'Understanding BAME and LGBTQ+ challenges'.

14. The HTA, HFEA, HRA and NHS resolution continue to offer reciprocal shared training opportunities, further addressing the need identified in the PDP's for more cross-organisational opportunities.

Wellness

15. A Wellness Programme of events is being developed to highlight health and wellbeing on a monthly basis throughout 2020. Topics will include: Health Awareness days, British Heart Foundation, Breast Cancer, Prostate Cancer etc., healthy eating, Mindfulness, lunchtime walks etc. There will be a topic focus each month.

Mental Health First Aider

16. We now have 14 members of staff (originally 15, one member of staff has since left the HTA) trained and certified as Mental Health First Aiders (MHFA). HTA-wide training is planned for 14 February to further build awareness in the role and how to access this important support.

Staff survey

17. The bi-annual staff survey opened for response on 18 November, facilitated by Capita. The first preliminary summary from Capita confirms a response rate of 87% which is higher than the previous staff survey of 2017 (81%). At the time of writing, the full analysis of the results had not yet been received by Capita. A further update will be provided during the course of the meeting.

Personal Development Plans (PDPs)

18. All staff have held and recorded a mid-year PDP review with their line managers.

Recruitment and retention

19. Our current retention rate is 64% based on a rolling year. Of the 12 leavers during this period, three were senior managers (Executive Senior Managers and Heads), four were Regulation Managers and 5 were of another grade.

20. We currently have four vacancies being actively recruited for:

    - Business Analyst and Project Manager. Both these roles have proved a challenge to attract and secure the right candidate. As a consequence we have recommenced the recruitment stage.
    - Project Manager (Interim) and Corporate Governance and Risk Manager (Interim) are also at the recruitment stage.

21. In addition, two Regulation Managers, the Organ Donation Manager and the Policy and Communications Officer have either left, or are currently working their notice periods. The SMT and Head of HR are reviewing these roles against current and projected skill gaps to assess the most appropriate use of this headcount.

22. The Data Analyst role has been filled as of 6 January 2020.

23. An interim HR Manager started with the HTA 14 November and has supported in the development of remote working contracts and policy.

HR Policies

24. The development of a Remote Working policy, Social Media policy, and Diversity policy to incorporate Disability, Gender and Ethnicity and Menopause policy are all close to completion and were submitted to the SMT through January for approval.

Other

25. The HTA is reviewing current procedures with a view to being recognised as achieving Race at Work Charter and Disability Confident employer status. This work will be reviewed by the SMT during February.

Finance

Financial position for Q3 2019/20

Table one: summary position

Summary Management accounts for the period
For the Nine Months Ending 31 December 2019
Year-to-date

	Actual	Budget	Var	Var	Forecast
	£'000s	£'000s	£'000s	%	£'000s
INCOME					
Government Grant in Aid	680,275	752,025	71,750	(29.26%)	**890,700**
Licence Fee income	3,716,974	3,716,405	(569)	0.02%	**3,676,274**
Devolved Governments	133,572	136,011	2,439	(1.79%)	**133,572**
Rental income	314,825	277,452	(37,373)	13.47%	**406,773**
Other income	35,096	33,750	(1,346)	3.99%	**46,796**
TOTAL INCOME	**4,880,742**	**4,915,643**	**34,901**	**(3.73%)**	**5,154,114**
OPERATING COSTS					
Staff costs (salaries etc)	2,318,169	2,428,551	110,382	(4.55%)	**3,072,253**
Other staff (exc inspection)	103,725	97,100	(6,625)	6.82%	**183,485**
Authority costs	135,094	148,955	13,860	(9.30%)	**181,078**
Inspection costs	33,804	82,500	48,696	(59.02%)	**51,804**
LODT costs	6,428	6,750	322	(4.78%)	**8,428**
Communication costs	12,044	25,475	13,431	(52.72%)	**39,374**
IT and Telecom costs	253,367	255,810	2,443	(0.95%)	**498,867**
Office and Administration	79,448	54,842	(24,606)	44.87%	**99,861**
Other costs	40,950	44,625	3,675	(8.24%)	**74,450**
Legal and Professional costs	22,108	30,000	7,892	(26.31%)	**52,108**
Accommodation	369,905	610,125	240,220	(39.37%)	**578,780**
Non-cash	160,720	149,250	(11,470)	7.69%	**214,378**
Total operating costs	**3,535,764**	**3,933,983**	**398,219**	**(10.12%)**	**5,054,867**
Net Income/(expenditure)	**1,344,978**	**981,661**	**(363,317)**	**21.91%**	**99,247**

26. Table one above provides a summary position at the end of quarter three of the 2019/20 financial year, and shows a year-to-date net surplus against budget of **£363k.**

Income

27. Table two details income to date and shows a variance to budget of **£34k** (0.71%) below budget. The small variance to budget overall is made up of shortfalls in our Grant in aid **(£72K),** the result of changes to the mechanism for funding and paying the increased NHSPS employers pension contributions and the profile of cash to be drawn down. This change in treatment does not impact on the net cost to the HTA.

28. Within licence fee income, short-falls in the Human Application and Post Mortem sectors, of **£74k and £7.5k** respectively**,** are a result of licences that have been revoked, or accounts written off (establishments who have entered into liquidation) or where activities have changed after the budget was set.

29. Offsetting the shortfalls is income from applications that are not budgeted for and the increase in rental income now that resolution of the VAT issue is complete, and application fees which are not budgeted for.

30. It is not expected that there will be further adjustments to income in the last quarter of this financial year.

Table two: income summary

Member Income Summary

For the Nine Months Ending 31 December 2019

	Year to Date			
	Actuals	Budget	Variance	
	£	£	£	%
Grant In Aid				
GIA	532,000	603,750	(71,750)	-11.88%
Non Cash cover	148,275	148,275	0	0.00%
Sub-Total	**680,275**	**752,025**	**(71,750)**	**-9.54%**
Licence Fees				
Application Fees	73,000	0	73,000	0.00%
Anatomy	97,982	97,780	202	0.21%
Post Mortem	1,173,781	1,181,340	(7,559)	-0.64%
Public Display	21,810	20,760	1,050	5.06%
Research	670,622	662,550	8,072	1.22%
Human application	1,381,559	1,455,755	(74,196)	-5.10%
ODT	298,220	298,220	0	0.00%
Sub-Total	**3,716,974**	**3,716,405**	**569**	**0.02%**
Other				
Other income (Rent)	314,825	277,452	37,373	13.47%
Other income (Secondees)	35,096	33,750	1,346	3.99%
Devolved Assemblies	133,572	136,011	(2,439)	-1.79%
Sub-Total	**483,493**	**447,213**	**36,280**	**8.11%**
Total Income	**4,880,742**	**4,915,643**	**(34,901)**	**-0.71%**

Expenditure (by exception)

31. **Staff costs (salaries)** – year to date, staff costs which include agency staff are under budget by **£110k**. The underspend is due to vacancies that were carried across all directorates and in particular the Regulatory Development and Delivery directorates at senior and middle management levels.

32. **Board costs** – which include travel and subsistence and venue hire costs are below budget by **£14k**. This reduction is due to vacant Member' posts carried for a large part of this financial year

33. **Inspection costs** – which are costs of travel and accommodation for site visits continue to be below budget at **£49k**. The reason for this reduction may be in part due to the inspection schedule and changes in the mode of travel Regulation Managers are taking (a possible impact of the revised T&S policy).

34. **Communication costs** – are under budget due to spend within our media monitoring service being lower due to a renegotiated contract **£7k.** Underspends across business planning, stakeholder engagement and conference travel have also contributed this underspend.

35. **Office and Administration** costs – are overspent by **£25k**, the majority of which relates to licence fees written off.

36. **Accommodation costs** – are underspent by **£240k** which is the result of a reversal of accrual adjustments in respect of VAT and rent increases from 2017/18. This significant variance has contributed to the overall underspend for the year.

37. **Non-cash costs** – costs relating to depreciation and amortisation of the HTA's assets are showing an overspend against budget due to assets capitalised in year but not budgeted for.

Forecast outturn

38. Our forecast outturn currently shows an underspend of **£99k**. This position takes into account several planned projects that relate to moving to cloud based services, a review of data and intelligence arrangements, stakeholder evaluations and upgrades to our hardware.

39. The forecast outturn will change as the executive is in the process of committing further expenditure in support of our office move project.

Other key performance indicators

Debtors

Table Three: Debtors by sector

Sector	Number of accounts	Value of debt £	%ge
NHS	37	£184,216	79.0%
Government Bodies	0	£0	0.0%
Non-Government Bodies	21	£48,961	21.0%
Total	**58**	**£233,177**	**100.0%**

40. Outstanding debtors as at 31 December are **£233k.** This is 14% lower than the same period last year. However, the profile is similar with the majority of outstanding debts being from NHS organisations.

41. Of the outstanding amounts 19%, or £45k, relates to amounts that are over a year old.

42. At the last report to the Board the amount outstanding was £87,713 of which £17k was written off. The split between NHS and Other debtors is now 80% to 20% respectively.

Financial risks

Table Four: Risks and mitigations

Risk	Mitigating actions and controls
Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income	Periodic review of current licences and expected income. Budgets are adjusted accordingly.
An overspend or significant underspend may lead to a lack of stakeholder confidence in HTA's ability to manage resources effectively.	Monthly review of financial position and quarterly re-forecasting. Review of activities that can be deferred.
Unexpected increases in regulatory responsibilities	Prioritisation when work requirements change. DHSC funding if appropriate.
Management fail to set licence fees at a level that recovers sufficient income	Financial projections and cash flow forecasting and monitoring.

43. The above financial risks remain unchanged.

Digital, data and technology and working environment

Business technology and cyber risk

44. We have continued to maintain a stable Business Technology operating environment while we focus on improvement activities.

45. We also continue to actively monitor our infrastructure for vulnerabilities and apply the latest security and reliability updates on a monthly basis. We have also run an email phishing awareness session for all staff to explain the various forms in which phishing can occur, and some common signs to look out for when identifying scammers, and how staff can cautiously proceed.

Information and Data

46. The data analyst position has been filled and the appointee will join the HTA in January. The data analyst will support our data management and analysis capability and the development of business intelligence.

47. We have commissioned a review of our data and intelligence systems and processes. The review commenced in this quarter and will continue into quarter four.

Deployment KPI narrative

Performance against 2019/20 KPIs

48. KPI 8 and KPI 9 are marked as red due to the number of vacancies reported and the attrition rate for quarter three.

49. All other Deployment KPIs for quarter three are within target or tolerance and marked as green.

HTA Board paper

Date	6 February 2020	**Paper reference**	HTA (05/20)
Agenda item	12	**Author**	Matthew Silk, Head of Communications
Protective Marking	OFFICIAL		

Public Guide to Code of Practice F

Purpose of paper

1. To seek feedback from Members on the updated public guide to Code of Practice F, in light of the upcoming introduction of deemed consent in England from spring 2020.

Decision-making to date

2. The first editions of the public guides were published in 2017, following extensive internal consultation with Heads of Regulation and the Senior Management Team (SMT). The published versions were approved by the Authority.

3. The public guides have not been edited or updated since 2017, although a survey was run in 2018 to gather feedback from the public to ensure they were being understood, and to evaluate where any potential future changes may be required.

4. This paper was reviewed and approved by the CEO on 29 January 2020.

Action required

5. Members are asked to provide any thoughts or comments on the public guides to contribute to their final drafting.

Background

6. In 2017 the HTA developed and published its first tranche of public guides, with the intention of providing a resource to members of the public to help them to more simply

understand their rights and how the system works in relation to HTA's regulatory oversight.

7. With England moving to a system of deemed consent for deceased organ and tissue donation from spring 2020, the public guide relevant to this sector requires updating to reflect the change in law, and to be consistent with the professional HTA Code of Practice F.

8. Although we have tried to add detail where helpful for a reader who is not familiar with the updated HTA Code of Practice F, the public guide to the Code is not the primary source of information about the law change to deemed consent for members of the public to be aware of, that is the role of the public awareness campaign being run by NHS Blood and Transplant.

Next steps

9. Once any feedback from Members has been incorporated into the next draft, it will be shared with the HTA public panel for a views.

10. A final version will then be published on the day that Deemed Consent Act comes into force in England, alongside the revised Code of Practice F.

Appendix A – Public Guide to Code of Practice F (updated draft)

A guide for the public to the HTA Code of Practice F: Donation of solid organs and tissue for transplantation (parts one and two)

This guide to our regulation of organ and tissue donation is written to address 'you' as a potential donor who is interested in donating during your life, or after death.

It is intended to be read alongside HTA Code of Practice F (parts one and two*):

Code of Practice F (Part One) Living organ donation [*insert url*]

Code of Practice F (Part Two) Deceased organ and tissue donation [*insert url*]

Part one applies to living donation in England, Scotland, Wales, and Northern Ireland. In Scotland, consent for organ donation is referred to as "authorisation"; read more here [link to scottish gov ODT webpage]

Part two was updated in 2020 to reflect the introduction of a new system (commonly referred to as an "opt out" system, or "deemed consent") for deceased organ and tissue donation in England.

In Northern Ireland, deemed consent does not apply; consent must always be given expressly by the potential donor before their death, or by a nominated representative or a person in a qualifying relationship after their death (see Appendix A below).

The HTA does not have a role in regulating deceased organ and tissue donation in Scotland. You can read more about organ and tissue donation in Scotland here [link to Scottish gov ODT webpage].

Not Covered in this Guide or Considered Under Deemed Consent

- Body donation
- Organ and tissue donation for research

*** please note -** part two of this public guide relates to deceased organ and tissue donation in England and Wales only, as both operate under a "deemed consent" system for organ and tissue donation. However, if you live in Wales we recommend you consult the Code of Practice on the Human Transplantation (Wales) Act 2013 for further details.

Commonly used terms

Tissue and organs

Organs

Where we use the term organ, or organs, in this guidance, it refers specifically to a whole solid organ, or organs, including:

- Kidney
- Liver
- Heart
- Pancreas
- Lung

The general definition of what constitutes an organ in this context is a body part which has a specific vital purpose.

Tissue

Where we use the term tissue, this refers to all other various human materials that are not whole solid organs.

Tissue and Organs

When we refer to “tissue and organs”, this is to make it clear there is a combination of both.

Deemed Consent

When we say consent can be “deemed”, this means that where no decision is recorded or known for an individual who has died, their organs and tissue can be considered for donation and transplantation.

The role of the HTA

The HTA regulates the donation of organs, tissues and cells (other than reproductive cells), and provides advice and guidance about the law. The HTA was established in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent.

A system of deemed consent for organ and tissue donation after death is operational in England and Wales. This does not affect the HTA’s regulation of living organ donation.

Part 1 – Living Donation

Commented [MJ1]: This section remains unchanged

Consent

You must give valid consent before you can donate an organ. We make sure that all donors give valid consent as part of our regulation. If you are a donor, this means that you have agreed to donate voluntarily and that you understand what you have agreed to. We do this through Independent Assessor (IA) interviews with all donors and recipients. After the interviews, the IA will send their report to us for a decision. Living organ donation cannot lawfully go ahead without our approval.

Limits to Consent

You have the right to give or refuse consent to donate all or any of your organs or tissue for transplantation. This applies both during your life and after your death. The most common kinds of limits to consent include giving consent to donate specific organs, or an organ to a particular person during their lifetime.
If there are conditions on consent, any donation must comply with these conditions to be lawful. Only the donor can remove these conditions.
You cannot use conditions to limit the type or types of recipients. For example, you can't exclude recipients based on gender, race, colour, language, religion or political opinions.

Types of living donation

There are several types of living organ donation. The information you will receive about your donation will vary depending on the type of donation.

Directed donation	This is organ donation to a specific person where donor and the recipient have a pre-existing genetic or emotional relationship. For example, siblings or close friends.
Directed altruistic donation	This is organ donation to a specific person where the donor and recipient do not have a pre-existing genetic or emotional relationship. These cases will normally involve a third party. For example, a friend of a friend or a social networking site for matching donors and recipients. We have published guidance on matching websites and social media.
Non-directed altruistic donation	This is organ donation to an unknown person. In these cases, the donor and recipient are anonymous. This is almost always done by donating into the paired / pooled scheme to create a 'chain' of transplants.
Non-directed altruistic donor chains (paired/pooled scheme)	This is also known as a paired / pooled donation. This is also organ donation to an unknown person. NHS Blood and Transplant (NHSBT) matches two or more donors and recipients so they can carry out a chain of operations. The remaining organ at the end of the chain is then donated to the best matched recipient on the national waiting list.

Please refer to our website for further information on the different types of organ donations.

Information you will receive

You should receive the information you need to reach a decision that is right for you. This information should be clear and suitable for your understanding about organ donation. It should also include information on any material risks. Material means a risk which:

- you reasonably think is significant to making a decision, and
- your clinician would reasonably think you would consider significant. Based on the information you receive, you should understand the particular risks and benefits in your circumstances, as well as in general.

The transplant team must also discuss the following with you:

- The surgical procedure, including any material short or long-term risks and the risk of death.
- The donation is voluntary - you should not be pressured into donating by anyone.
- The transplantation is not always successful - you should be told the likelihood of success for the transplant, the health benefits for the recipient as well as any side effects or complications.
- That you have the right to withdraw your consent at any time - you should also be told what this may mean for you and the person receiving your organ.

- That it is illegal to seek or receive payment or reward for donating organs for transplantation.
- You can be reimbursed for expenses resulting from your donation - this might include travel costs or loss of earnings.

Additional information for non-directed altruistic or paired/pooled donors

If you are a non-directed altruistic or paired/pooled donor, you should receive further information about how these systems work. For example, how suitable matches or recipients are found.

In addition, for these types of donations, your identity and the identity of the recipient must remain confidential. You are not allowed to know who will receive your organ until after the transplant. Similarly, the recipient will not know your identity.

HTA Approval process

If you are assessed as a suitable donor, you will be referred to an IA. A suitable donor is someone who is medically suitable to donate and who has given informed consent.
IAs act as a representative of the HTA. They will interview you and the recipient to check the requirements of the Act are met. In most cases, the donor and recipient interviews are carried out together and separately. In non-directed cases, the donor and recipient will not be interviewed together. If you are a donor, the IA will first of all check you understand the surgical procedure. This includes the risks involved. The IA will also check that you are aware that you can withdraw consent.

As part of your interview, the IA will check that:

- you are not being forced to do something against your wishes;
- you have not asked for, or been offered a reward; and
- you have made an informed decision.

Following the interviews, the IA will submit a report to us to make a decision. If you are not happy with the decision, you can ask for a review.

Further information about our approval process is available here.

If you have any concerns about the services you've received, please contact the HTA on either 020 7269 1900 or by using our online form.

Part 2 – Donating organs after death

(**Please note** – this public guide only refers to deceased donation of organs and tissues in England and Wales)

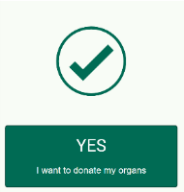
From spring 2020 the consent requirements for deceased organ donation in England changed to what is commonly referred to as an "opt-out" system. In Wales, this system has been in place since 2015.

What this means is that where no decision has been recorded to either opt in or opt out, and a decision is not known, consent can be deemed (that is, it can be deemed that an individual would have agreed to donation), and organs and tissue may be used for donation and transplantation after death.

What do I need to do?

You should make your decision about donation, tell your family and close friends and:

- if you have already recorded your decision, you do not need to do anything else;
- if you have not recorded a decision, and you wish to become an organ and tissue donor, you do not have to record your decision, as it can be deemed. But you might want to make it clear, or;
- if you have not recorded a decision, and you do not want to become an organ and tissue donor, you should record your decision to opt out of organ and tissue donation.



Consent for donating organs and tissue after death

The HTA is responsible for providing guidance on what counts as lawful consent.

Consent must be provided to allow organ and tissue donation to happen lawfully, but it does not mean donation must happen. This is a clinical decision in which your family play a crucial role.

During your life, you can consent to donate in several ways:

You can specify your wishes in writing.

- The most common way to do this is by registering your decision on the Organ Donor Register (ODR), which is run by NHS Blood and Transplant (NHSBT), and is checked in every case where organ and tissue donation is possible.

- You can also access the ODR to record your decision via the NHS App

- You can nominate a representative to make your wishes known after your death (read more here)

You can withdraw your consent at any time.

Please note - consent cannot be deemed for non-transplantation purposes, such as research; this is outside the scope of deemed consent. Express consent will always be sought.

Opting out of organ and tissue donation

If you make it known that you do not consent to organ and tissue donation, then donation cannot lawfully go ahead. No one can override this decision after your death. The same rules apply for any child who can make a decision (see HTA Code of Practice F (page X) for more information on children and consent [insert url]).

If your decision is not known, the hospital will first check if you nominated a representative, who would lawfully be able to make a decision on your behalf.

For children who had not made their decision known, the consent of a single parent is enough for lawful donation.

If no representative has been nominated, someone in a 'qualifying relationship' to you immediately before your death can give consent. This consent can be withdrawn at any time up until the donation itself.

Although you do not have to record your decision via the ODR, it is consulted in every case. Your family and close friends will also be consulted before any donation proceeds.

What does my consent cover?

You can consent to offer all your organs and tissue for donation after your death, or you can specify which organs you consent to donate.

You cannot specify a particular type of person that you wish to donate to. NHSBT (the organisation responsible for organ allocation) does not accept organs where a restriction is requested (for example age, gender, race, religion).

Sometimes, even when consent is in place, donation cannot go ahead. There are many reasons why this may be the case.

Further Information and Resources

Organs not included under deemed consent

Consent cannot be deemed for some types of organs and tissue.

In 2019, the Department of Health and Social Care (DHSC) consulted on which organs and tissue would require express consent for transplantation (referred to as “novel transplants”).

You can see the list of organs and tissue requiring express consent on the HTA website here [*insert url*].

Excepted Groups (people whose consent won’t be deemed)

Consent cannot be deemed in England if you are a child (under 18 years old), or fall under one of the following excepted categories:

- An adult who had **not been ordinarily resident** in England for a period of at least 12 months immediately before dying, or;
- An adult who **lacked the capacity** to understand the notion of deemed consent for a significant period before their death.

For more details on what “ordinarily resident” means, or how capacity is decided, please see HTA Code of Practice F Part Two [*insert url*].

Religious Perspectives on Organ and Tissue Donation

Discussions with your family will take place before any donation goes ahead - even if you have recorded your decision to opt in to organ and tissue donation. This is to confirm your decision on organ and tissue donation.

This will take into account your faith and/or beliefs - cultural, spiritual, religious or non-religious – as this is an important part of person-centred care.

These discussions should seek to involve individuals who are familiar with the faith and/or beliefs of the potential donor. Some hospitals will have staff who have received special training about different faiths.

If you register your decision on the ODR you can request also request that your family should be spoken to about how organ and tissue donation can go ahead in line with your faith or beliefs.

Further information on religious belief and faith in relation to organ and tissue donation can be found on NHSBT's website here: https://www.organdonation.nhs.uk/helping-you-to-decide/your-faith-and-beliefs/.

Appendix A - Qualifying relationships

Commented [MJ2]: This section is unchanged

The Human Tissue Act 2004 includes a list of 'qualifying' relationships, which are ranked.

When consent is sought for any process, the person nearest the top of the list should be asked first to give consent for removal, storage or use of relevant material. Their decision has priority over someone below them on the list. The list is as follows:

1. Spouse or partner (including civil or same sex partner)
2. Parent or child
3. Brother or sister
4. Grandparent or grandchild
5. Niece or nephew
6. Stepfather or stepmother
7. Half-brother or half-sister
8. Friend of long standing

For these purposes, a person is considered a partner if they if live as partners in an enduring family relationship.

While the Human Tissue Act is clear on the hierarchy of relationships, there may be situations where relatives disagree on giving consent.

There are procedures and advice on dealing with these conflicts in Code A: Guiding Principles and the fundamental principle of consent, paragraphs 30-39.

HTA Board Paper

Date	6 February 2020	**Paper reference**	HTA (06/20)
Agenda item	13	**Author**	Ruth Joyce Senior Policy Manager
Protective Marking	OFFICIAL		

Deemed Consent- Outline of the Consultation Response and Next Steps

Purpose of paper

1. To provide the HTA Board with an outline of the planned consultation response document, which will capture the changes made to the revised Code of Practice F in response to the 12 week consultation held from 4 July until 26 September 2019.

Decision Making

2. This report was approved by the CEO on 27 January 2020.

Action required

3. Members are asked to note the proposed plan and provide any feedback or on the suggested content and approach.

Legislative Background

4. The Organ Donation (Deemed Consent) Bill 2017-2019 received Royal Assent on 15 March 2019. The Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) will come into force in May 2020.

5. The Deemed Consent Act will only apply to 'permitted material'; the Department of Health and Social Care (DHSC) has consulted on Regulations which specify the material which will not be covered by deemed consent. The Regulations will be subject to Parliamentary approval.

6. The Deemed Consent Act places a duty on the HTA to provide practical guidance for professionals working in the field of organ donation and transplantation on deemed consent. The amended Code of Practice F has been approved by the Authority and provided to DHSC colleagues to begin the Ministerial clearance process. Parliamentary approval will also be sought prior to the legislation coming into force in May.

7. A consultation response document is being developed which will set out the changes and additions that have been made as a result of consultation and will also outline why other suggested amendments have not been made.

Consultation and outcome

8. Under section 26(5) of the 2004 Act, the HTA is required to consult before producing its Codes of Practice. The HTA carried out a consultation from 4 July 2019 until 26 September 2019. Several meetings and several face-to-face engagement events were held with stakeholders before and during the consultation.

9. A total of 75 responses were received during the consultation. A wide range of stakeholders, both individuals and organisations, put forward their views. This included clinicians, specialist nurses, transplant surgeons, charities, faith and secular organisations, professional bodies, academics and members of the public.

10. An outline analysis is included in the following sections which will form the basis of the consultation response. The response document will also include graphs and tables in an accessible format to highlight key findings.

Key themes arising from the consultation

11. The consultation identified several areas where extensive revision was required. Specifically, there was comprehensive feedback and advice received on:

    - The role of the family;
    - Faith and cultural considerations;
    - Advice to clarify specific terminology used throughout;
    - Advice to restructure some paragraphs and content for clarity;
    - Advice to remove repetition and text that did not add value; and
    - A desire for there to be more working examples.

How the Code was amended to reflect consultation responses

12. A new introductory section and a scope section have been added which clarify, in particular, new legal terms introduced by the Organ Donation (Deemed Consent) Act

2019, along with additional information on the HTA's remit with regards to organ and tissue donation and transplantation. The interpretation and general guidance section has been extensively revised to explain all terms of substance that appear throughout the Code of Practice. In particular, this section refers to the role of the Specialist Nurses, and, following feedback, makes clear what is meant by the terms 'family' and 'information'. Terminology that is applicable in a deemed consent scenario including 'ordinarily resident' and 'significant period' have also been defined. Any term that is not specifically defined, but where comments were received seeking clarity, have been included in the glossary.

13. Substantial feedback was received on the role of the family in an organ and tissue donation scenario. This has been addressed by providing clarity on what is meant by 'family' at the beginning of the Code of Practice and throughout. Some respondents felt that the Code of Practice should make clear the requirement to establish consent before the family is asked to provide information relevant to organ and tissue donation. This section has been re-worked into a more logical order to reflect this. There was consultation feedback that some paragraphs in this section could be interpreted to be contradictory and have therefore been revised for clarification. The position when there is no family for professionals to speak with, in both an expressed consent scenario and a deemed consent scenario, has been outlined in more detail following extensive engagement with professional colleagues.

14. The faith and beliefs title and section has been extensively revised. This follows written feedback received during the consultation, as well as a number of face-to-face meetings with faith and belief groups held by the Chief Executive. Specific language and tone has been sensitively amended. This follows feedback that the Code of Practice should clearly recognise the seriousness and sincerity of people's non-religious beliefs, and wording has been amended to reflect this. Feedback was received on appropriate terminology to indicate individuals who may provide support in discussions around faith and beliefs and this has been amended. Information regarding special arrangements that some faith and belief groups may have in place, including dedicated telephone helplines in some instances, has been added. The role of the faith declaration on the ODR has been clearly outlined, as well as the conversations that the specialist nurse will have with the family in relation to faith and beliefs.

15. Substantial positive feedback was received during the consultation about the usefulness of examples within the Code of Practice. However, there were requests for additional specific examples. Additional examples have therefore been added, moving from five examples to nine.

16. Flowcharts have been added to the back of the document as professional feedback was received to demonstrate that these are particularly helpful in practice.

17. Consultation feedback from several respondents was that the role of coroners should be included and a paragraph has been added.

18. Some respondents suggested it could be made clearer that deemed consent does not apply to organs and tissue used for research. To provide clarity, a section on this has been added.

19. Some respondents felt that the Code of Practice did not sufficiently reference tissue donation and instead focussed on organ donation. The Code of Practice has been amended throughout to reflect this feedback and a new section on tissue donation has been added.

20. Some respondents felt that the responsibility placed on the Specialist Nurse for Organ Donation was too great and that the Code of Practice could be interpreted to suggest that crucial decisions could be made by nursing professionals in isolation. The Code of Practice has been amended to make clear that shared decision making processes will be in place and that before any critical decision is made, discussions with clinical colleagues and the family will take place.

21. The order of the Code of Practice, including some sections, sub sections and paragraphs, have been amended to ensure the flow of information is as logical for the reader as possible. The order follows the donation pathway as far as is practicable. Areas of duplication have been reduced or removed entirely.

22. Hyperlinks have been added throughout where requested following consultation feedback.

Next Steps

23. The consultation response document will be completed and circulated for review and approval by Authority members via correspondence in due course.

24. Draft directions have been written to revoke the previous editions of Code A and Code F and bring into effect the new Codes in May 2020.

25. The consultation response document, Codes of Practice A and F and the Public guide to Code F will be published together on the HTA website in May 2020.