HTA Human Tissue Authority

Eighty-ninth Meeting of the Human Tissue Authority

Date 18 July 2019
Time 10.00 – 15.00
Venue Viceroy Suite
Grosvenor Hotel, 101 Buckingham Palace Rd, London SW1W 0SJ

Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 9 May 2019 meeting	HTA (15/19)
4.	Confidential Minutes of 9 May 2019 meeting	HTA c(05/19)
5.	Matters arising from 9 May 2019	Oral
	Regular Reporting	
6.	Chair's Report	Oral
7.	Chief Executive's Report	HTA (16/19)
8.	Delivery Report – Quarter One 2019/20	HTA (17/19)
9.	Development Report – Quarter One 2019/20	HTA (18/19)
10.	Deployment Report – Quarter One 2019/20	HTA (19/19)
	Committee and Advisory Group Reporting	
11.	Stakeholder and Fees Group	HTA (20/19)
12.	Audit and Risk Assurance Committee	HTA (21/19)
13.	Histopathology Working Group	Oral
	Policy Issues	
14.	Code of Practice for Deemed Consent in England and Novel Transplants	Oral
15.	The Future of the Delivery Report	HTA (22/19)
16.	HTA Office Relocation Business Case	HTA (23/19)
17.	Out-of-hours Consideration of Emergency Living Donation Cases	HTA (24/19)
18.	Licensing Fees Review	HTA (25/19)
	Any Other Business	
19.	Electronic Authority Packs	Discussion

	Lunch	

Meeting close 12.45
Lunch 12.50 - 13.30

Afternoon Session- 13.30– 14.00
Establishing Member training needs and interests- Member discussion

Minutes of the eighty-eighth meeting of the Human Tissue Authority

Date 9 May 2019

Venue Etc Venues, One Drummond Gate, Pimlico

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Present	
Members Dr. Hossam Abdalla Dr. Stuart Dollow Amanda Gibbon Prof. Andrew (Andy) Hall William (Bill) Horne (Interim Chair) Glenn Houston Prof. Penney Lewis Prof. Anthony Warrens Bishop Graham Usher Dr. Lorna Williamson, OBE	**In attendance** Allan Marriott-Smith (Chief Executive) Nicolette (Nicky) Harrison (Director of Regulatory Delivery) Dr. Hazel Lofty (Director of Regulatory Development) Richard Sydee (Director of Resources) Ruth Joyce (Senior Policy Manager) (item 12) Nima Sharma (Board Secretary; minute taking) **Observers** Gisela Botelho, Business Support Manager Eliza Drury, Transplant Manager (Interim) Ravinder Chana, Regulation Officer

Item	Title	Action
Item 1	**Welcome and apologies**	
	1. Bill Horne (the Interim Chair) welcomed Members, attendees and observers to the eighty-eighth meeting of the Human Tissue Authority (HTA). The Interim Chair explained that the meeting was a public event designed to promote transparency and good governance in the HTA's proceedings. Observers were assured that they would be given the opportunity to ask questions at the end of the meeting and that photographs would be taken during the	

	event. 2. There were no apologies received from Members but they had been received from Jeremy Mean and Jacky Cooper of the Department of Health and Social Care.	
Item 2	**Declarations of interest- Oral**	
	3. The Chair asked Members if they had any personal or pecuniary interests to declare in relation to items of the meeting's agenda. The Chair disclosed one interest regarding a familial relationship to an individual involved with the production of perfusion devices in the USA, which were sold globally. 4. There were no other interests declared.	
Item 3	**Minutes of 7 February 2019 meeting- (09/19)**	
	5. The Chair requested Members' comments on the minutes for accuracy. 6. Following earlier responses by Members, paragraphs 33, 61, 72 and 75 were to be amended. Members were provided with a document containing the proposed amendments which were all accepted. 7. An additional action was added to the minutes in relation to paragraph 44. 8. Following the above amendments the minutes were accepted as an accurate record of the meeting.	
Item 4	**Matters arising from 7 February 2019 meeting**	
	9. The Chair noted that all actions from the 7th of February 2019 Authority meeting were resolved, ongoing in nature or would be addressed by the Senior Management Team (SMT) during the meeting. 10. The Chair noted that the CEO Report (02/19) of the February Authority meeting contained a typographical error at paragraph 11. This was in relation to the year of the DHSC Accountability meeting, which was incorrectly stated as 2018 when it should have been 2019.	

	11. There were no further matters arising highlighted.	
Item 5	**Chair's Report- Oral**	
	12. The Chair provided an oral report and opened by wishing Professor Dame Sally Macintyre all the very best for the future as her three year tenure had ended on the 4th of May. He informed members that he had written to her, thanking her for her contribution to the work of the Authority. 13. The Interim Chair also congratulated the Right Reverend Graham Usher following the approval by Her Majesty the Queen of his nomination to be the next Bishop of Norwich. 14. The Chair confirmed that interviews for the permanent HTA Chair will take place week commencing 14th of May. He also highlighted that the Department of Health and Social Care have advised that the closing date to recruit two new Members had been extended until the 20th of May with the aim of expanding the pool of applicants. The HTA will be involved in actively promoting these roles and members were asked to highlight the role with their networks. 15. The Chair informed Members that the HTA Strategy has been refreshed. 16. The Chair provided Members with an update on key meetings that have taken place since the last Authority meeting. These were; - Organ Donation and Deemed Consent Meeting, hosted by NHS Blood and Transplant, on the 9th of April; - A Multi Faith round table meeting on the 25th of February on deemed consent to organ donation ; - A visit to Facebook's offices by the CEO and Interim Chair which was to better understand how other organisations support staff who work remotely. 17. The Chair thanked Members and staff for their support in the delivery of the Multi Faith Round Table day, which all agreed had been very successful. 18. The Chair informed Members that the Deemed Consent Bill gained Royal Assent on the 15th of March 2019 with the law coming into force on the 6th of April 2020.	

	Action 1: To circulate the link to the recruitment campaign for new HTA Members to Authority Members.	NS
Item 6	**Chief Executive's Report [HTA 10/19]**	
	19. Allan Marriott- Smith presented this item and introduced this report. 20. Members were informed that four of the six strategic risks remained stable, however, there is upward pressure on risks three and four. Three posts remained unfilled at the end of April 2019 and were being redesigned to meet future capability needs. 21. Members were informed that there are two strategically important Heads posts that will need to be filled with some urgency: the vacant Head of Planning and Performance post and the Head of Human Resources, who is leaving the HTA on the 20th of June. Members were informed that it has proved difficult to attract suitable candidates. 22. Members were provided with an update on progress with the business case to access HTA reserves to fund the Transformation Programme. DHSC has advised that all pending business cases have been put on hold on HM Treasury advice. Members were informed that it will be unlikely that the HTA is given approval to release reserves in the 2019/20 business year and that a report on the implications of this will be provided to the Authority following full assessment. 23. Members were provided with key points from the Accountability meeting with the DHSC which took place on the 7th of May. This update included information about Regulation Manager recruitment, the HTA's re-location to new offices, the delivery of inspections in 2018/19, preparation for exit from EU and the success of the Annual Conference. 24. Members were provided with an update on GDPR compliance and were informed that the only outstanding action in achieving full compliance is migrating to the new HR system. The migration is due to take place before the 20th of June. 25. Allan Marriott-Smith informed Members about the Consultation on coronial investigations of stillbirths, initiated by the Government. This aims to seek views on whether Coroners should be given powers to investigate full term	

	stillbirths. The Histopathology Working Group consulted with Dr Hazel Lofty and although the HTA is not required to take a formal position on the consultation questions, the HTA will respond on matters within its remit. Members agreed it would be beneficial to see the draft consultation response. 26. Members noted the content of this report. **Action 2: The draft consultation response to be circulated to Members**.	ANH
Item 7	**Delivery Report- Quarter four 2018/19 [HTA 11/19]**	
	27. Nicky Harrison presented this item and introduced the report. 28. Members were informed that over 200 site visit inspections have taken place over 2018/19. HTA staff have done an excellent job in achieving this target in the face of a number of operating constraints. 29. Members were advised that the KPI summary at the beginning of the Delivery Report shows a clear pattern of consistently strong delivery over quarter four. Nicky Harrison also noted the position on KPI 4, concerning the timely management of Corrective and Preventative Action Plans (CAPAs), which is not RAG-rated, given that it partly represents HTA performance and partly the performance of those we regulate. Nicky Harrison also informed Members that the performance against the enquiries KPI has seen an improvement during quarter four, despite some of the enquiries being complex. She was pleased to note that all RAG-rated KPIs were green for quarter four. 30. Members were updated on the progress that has been made in reviewing the induction process for new Regulation Managers (RMs), with helpful facilitated feedback from the past year's cohort of new RMs being used to inform this work, which will be taken forward by Heads of Regulation working with the newly-appointed Regulation Manager-Training (a new role). 31. Members were informed that the HTA received and dealt with 15 FOI requests in quarter four in a timely manner, almost double the number received in the previous quarter, with many being complex.	

	32. Members were asked to note content in pages 3 to 5 of the report which provided more information about formal regulatory matters such as critical shortfalls and Regulatory Decision Meetings, and pages 6 onwards, which contained information about stakeholder engagement activity, including some valuable collaborative working with other professional bodies (such as the Association of Anatomical Pathology Technologists) and working with colleagues from devolved administrations. 33. Members questioned whether the system for responding to enquiries is becoming more efficient in light of the improvements seen in the KPI for enquiries in quarter four. Nicky Harrison informed Members that it was not necessarily clear why there had been an increase in performance but it was interesting to note that this had occurred despite what appeared to be an increase in the number of complex enquiries, for example relating to the UK's exit from the EU. She highlighted that the Head of Communications had led on ensuring that training on enquiries management was included in a Regulation Training Day in early January, attended by all staff in Regulatory Development and Delivery, and that this had doubtless helped improve our approach to handling and managing enquires. 34. The Right Reverend Bishop Graham Usher noted the increase in Human Application (HA) Serious Adverse Events and Reactions (SAEARs) and questioned whether further information could be provided about the nature of these incidents in future Delivery Reports. Nicky Harrison confirmed that the HTA reviews all SAEARs reports in detail and maintains data from which trends are identified, which enables the HTA to work actively with Licensed Establishments on individual incidents and to work with the sector and other regulators and competent authorities to identify and respond to emerging trends that could indicate emerging risks. Members agreed that it would be helpful for the Delivery Report to give more information about trends. 35. Members agreed that a paper should be brought to the next Authority meeting to propose how the Delivery Report could be re-structured to give a clearer insight into regulatory delivery and how the HTA had been using data (such as from reportable incidents across sectors) to inform risk analysis and manage regulatory activities. Members also agreed that the regulatory-focused communication and stakeholder engagement activity carried out by the HTA, which it was hoping to extend through the blog functionality,	

	was a useful way of sharing such information and insight which could help address these risks. 36. Members raised questions about whether it is appropriate for Authority Members to be on-call to consider emergency out-of-hours living donation cases. The Chair canvassed the opinions of Members about whether they should continue to have this responsibility, following which he proposed that this be discussed at the next meeting. Members asked that the requirement to be on-call be drawn to the attention of candidates selected for interview in the current recruitment round. 37. The Authority noted the content of the report. **Action 3: A paper to be brought to the next Authority meeting to set out a proposal as to how the Delivery Report could be restructured so that it provides a clearer narrative of regulatory activity, such as showing trends and the HTA's assessment of and response to any changes in regulatory risk which these might indicate.** **Action 4: A paper to be brought to the next Authority meeting setting out the background to, and rationale for, Member involvement in the on call rota to support a discussion about the benefits, risks and concerns with the current process.**	ANH NS
Item 8	**Development Report- Quarter four 2018/19 [HTA 12/19]**	
	38. Dr Hazel Lofty presented this item and introduced the report. 39. Dr Lofty provided Members with an update on development activity in quarter four and confirmed that progress had continued with the deemed consent legislation and EU exit preparedness work. As a result, other areas of non-discretionary work have been put on hold. 40. Members were informed that there is residual work to be done with the CRM upgrade, which encompasses minor system changes. 41. Members were provided with an update about the Licensed Establishment Engagement Programme and were informed that steady progress has been made. Dr Lofty extended her thanks to Professor Andy Hall and Dr Stuart Dollow who have provided their support. Members were informed that the online tests were launched on the 28th of March and had already been taken over 1,000 times. She thanked	

	Members for their continued engagement with the HTA blog. 42. Members were informed that the Senior Management Team (SMT) are considering a paper on developing learning resources for Designated Individuals (DIs) which includes reviewing a range of options, including how the HTA's website can be utilised. Dr Lofty agreed to provide an update at the next meeting. 43. Members were provided with an update on the HA risk work and informed that work was progressing on our approach to providing oversight of Third Party Agreements (TPAs) and the authorisation of Preparation Process Dossiers (PPDs). Dr Lofty informed Members that she expects this work to continue throughout the year. 44. Members raised questions about key risks relating to machine perfusion of organs. Dr Lofty informed Members that there is a great deal of interest in using machine perfusion, which reduces the organ's cold ischaemic time. The HTA will need to consider how this information is reviewed during audits. Members were informed that data from machine perfusion devices could potentially form part of the organ characterisation. 45. Dr Lofty informed Members that the HTA is ready to take forward its EU Exit preparedness activity pending further government decisions. The HTA's Operational Readiness has been marked as green by the Department of Health and Social Care. 46. Members noted the content of this report. **Action 5: Dr Hazel Lofty to provide an update about the proposals for provision of learning material for DIs at the next Authority meeting.**	HL
Item 9	**Deployment Report- Quarter four 2018/19 [HTA 13/19]**	
	47. Richard Sydee introduced the report. 48. Allan Marriott-Smith provided an update on the proposed changes to the pay framework. He informed Members that the planned introduction of office-based and home-based pay scales, and the associated contractual changes, will not now take place in the current financial year, but will be	

	timed to coincide with the move to new office premises in 2021. In the meantime there will be a review of the flexible working policy and the introduction of a new working from home policy. 49. Richard Sydee highlighted that Paragraph 22 of the report provided an explanation about how debtors are paid and afforded Members assurance on this point. 50. Members were informed that increased spend resulted from additional resource secured in the last quarter from the DHSC and that the HTA had ended the financial year in the expected position, subject to final audit sign off, of £80,000 surplus. 51. Richard Sydee referred Members to paragraph 30 of the report. He informed Members that the figure presented should read £250,000 and apologised for this error. 52. Members were provided with an update on the relocation of the HTA's offices and were reminded that the HTA must vacate its premises by the 31st of March 2021, as formal notice has been issued. There are plans in place to initiate the move, however, a formal business case will be brought to the Authority to consider. Richard Sydee informed Members that the space in the new offices will be of a high quality and that there are more on site meeting facilities which should support better integration of staff and Authority Members and reduce expenditure on outside venues. 53. Members referred to the Business Technology section of the report and highlighted their concerns that 292 vulnerabilities had been identified; in which 33 were high impact. Dr Hazel Lofty reassured Members that there are no unresolved critical vulnerabilities. Members were informed that these were associated with legacy servers which have now been decommissioned and that there are plans to work through the remaining cyber security issues. 54. The Authority noted the content of this report.	
Item 10	**Audit and Risk Assurance Committee (ARAC) [Oral]**	
	55. Amanda Gibbon provided an oral update on key points from the meeting on the 12th of February. During the update she confirmed that: - there have been no new internal audit reports, however,	

	the Committee has discussed progress against cyber security audits. - the 2019/20 audit report has been approved. - a new risk 6 has been added to the Strategic Risk Register. - HA risk work is underway and the Committee is maintaining oversight of developments on Third Party Agreements. - a deep dive into the preparedness for the transformation programme was undertaken. Although there was a lack of concrete proposals at the time, the committee felt it was still helpful. - during the forthcoming June meeting, the Committee will be considering the annual governance statement, records management and GDPR. The deep dive will focus on DI engagement. The workshop in the afternoon will review the way in which risks are recorded. 56. The Authority noted the content of this update**.**	
Item 11	**Transplant Advisory Group (TAG) [Oral]**	
	57. Professor Anthony Warrens provided an oral update on key points from the meeting on the the 8th of May. During the update he confirmed that: - progress has been made on completing work packages for the Independent Assessor (IA) Sustainability project. He informed Members that there remains variability in remuneration for this role amongst NHS Trusts. - there is an emerging trend of units seeking swift turnaround times for decisions on cases (shorter than target service levels), including requests for urgent panel decisions. TAG Members agreed that the HTA should continue to consider such cases whenever possible to support the clinical teams. 58. The Authority noted the content of this update.	

Item 12	Introduction of Deemed Consent [HTA 14/19]	
	59. Dr Ruth Joyce presented this paper. 60. Members were informed that Code F was sent to Authority and TAG members last week and that a number of comments and proposed amendments to the Code were received. Dr Joyce thanked Members for their contribution to the amendment of the draft Code. 61. She highlighted to Members that a number of policy issues were discussed at the TAG meeting, in particular, the approach to be taken in situations where no information is recorded about a person's decision with respect to organ donation and there is no family available to consult. 62. Members agreed that the Code must be clearer on what the legislation permits and prevents in such cases, whilst balancing the fact that in practice donations do not generally proceed in these circumstances. Members agreed that the relevant paragraphs within the Code be reviewed to provide greater clarity around this key issue. 63. Members also noted that as the legislation intends to optimise the number of organs donated, it is crucial for the information to be concise, to reduce the risk of losing organs that could be transplanted. 64. Members agreed to discuss further changes in Code F through teleconference if this proves necessary. 65. Members also noted that further work needs to be carried out on tissue typing prior to seeking consent to proceed with organ donation. 66. The Chair thanked Dr Joyce and her colleagues for the work carried out to date on this issue. 67. Members noted the content of this paper.	
Item 13	**White space for discussion [Oral]**	
	68. This item was designated for members of the public to ask questions of the Authority and Executive. Issues raised ranged from the potential impact on body donation following the introduction of deemed consent, to the use of acronyms by officials at public meetings.	

	69. At its conclusion the chair thanked the members of the public who had attended for their interest and involvement.	
Item 14	**Any Other Business [Oral]**	
	70. There being no other business proposed, the chair brought that section of the meeting to a close**.**	

Next Authority meeting:

Thursday 18 July 2019

Authority paper

Date	18 July 2019	**Paper reference**	HTA (16/19)
Agenda item	7	**Author**	Allan Marriott-Smith
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Chief Executive's Report

Purpose of paper

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 Authority meeting on May 2019.

Decision-making to date

2. This report was approved by the CEO on 4 July 2019.

Action required

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

Overview of Strategic Risks

4. Five of the six strategic risks (found in **Annex A**) were assessed to be stable as of June 2019. In its June assessment, SMT were of the opinion that the overall risk for Risk 1, Failure to regulate appropriately, has reduced as all Regulation Manager (RM) posts are filled and all RMs recruited in the preceding year have now been signed-off to lead inspections.

Other Issues

HTA Development Programme 2019 to 2021

5. Members will be aware that the business case for funding the planned Transformation Programme will not be proceeding in 2019/20. As a consequence, the Executive has begun the task of planning which change activities from the proposed programme will need to be carried out between now and April 2021.

6. At a meeting on 27 June, SMT and those Heads of function most closely involved in the Programme agreed:

    - That the language "HTA Development Programme" will be used to describe our change programme over the period to 2021. This was on the basis that we will not be able to fund transformative change, but also that the changes (e.g. office move and related changes to working practices) will be more significant than continuous improvement.
    - A draft set of criteria on which to establish relative priorities within the long list of change activities that have been proposed.
    - To undertake an initial mapping against these criteria to assess what this implies about activity which Must, Should, Could and Won't (MoSCoW analysis) be undertaken in the period to April 2021. In light of the funding constraints, this will almost certainly mean that change activities proposed in previous strategies agreed by the Authority will need to be scaled back or stopped.

7. Members should note that since this June strategic risk assessment was undertaken, the Director of Regulatory Development (the SMT lead for this work) has resigned from the HTA. This will increase the risks associated with the planning and execution of the HTA Development Programme in the period until a new appointment is made.

Authority Strategy away day

8. The Authority Strategy away day will be taking place on the Thursday 3 October 2019. The venue is still to be confirmed. The main areas of focus for the day will be on issues stemming from the MoSCoW analysis referred to in paragraph six.

9. During its discussion on the 12 June 2019, the Audit and Risk Assurance Committee Meeting, Members concluded that proposed change activities can also be viewed as a reaction to risk (either mitigating a negative, or failing to exploit an opportunity). As such, decisions about what is in and out of the HTA Development Programme, will also prompt a discussion about the risks that the Authority is willing or required to tolerate. The discussion on the day will be used to come to a shared view on risk tolerance.

10. The away day will also present the initial recommendations on changes to licence fees made by the Licensing Fees Working Group. There will also be a session to bring Members up to date with the HTA values refresh work.

Authority Chair and Member Appointments

11. The competitions to recruit a new permanent Chair of the HTA and two new Members were launched on 28 March. Interviews for both competitions have been completed. At the time of writing there had been no announcement of the successful candidates for any of the posts. An oral update will be provided at the meeting.

All staff away day

12. An all staff away day took place on Monday 17 June at the Grosvenor Hotel. The first half of the morning focussed on changing the way in which the HTA works and the second half focussed on the HTA's response to managing work-related stress and on the plans to refresh the HTA's values. The following content was covered:

- HTA Staff were provided with an update on future office accommodation following a visit, by the Head of Business and IT and the Business Support Manager, to the Department of Health and Social Care's Offices in Leeds (HTA 18-19).

- The Flexible Working (HTA-POL-010) and Home Working (HTA-POL-046) Policies were circulated to HTA staff in June and a short session held, to highlight the key points from these policies to HTA staff. These policies aim to formalise expected practice for flexible and home working.

- A discussion on the HTA's plans for its future pay framework took place following feedback from HTA staff that certain aspects remained unclear following the away day in March 2019.

- An interactive session took place on stress management, with a particular emphasis on the expectations of the role of the Mental Health First Aider. There was also some focus on how stress can be better managed in the organisation.

- HTA staff were provided with an update on the plans to shorten the length of site visit inspection reports as a way to reduce the workload. A review will also focus on placing information that has historically been drafted into the report, in other areas such as CRM so that the information is still accessible to Regulation Managers planning future inspections.

- An interactive session to kick off the refresh of the HTA's organisational values.

Quarterly Accountability meeting to DHSC

13. The HTA met with DHSC on Thursday 11 July 2019 as part of its regular quarterly accountability arrangements. An oral update on the outcomes will be provided at the meeting.

14. Minutes of the quarter four Accountability meeting on the 2 May 2019 have been circulated with the Authority papers for information.

Internal Audit

15. Fieldwork was completed on the utilisation of capabilities internal audit, which is the only 2019/20 quarter one audit on the audit plan. The report on this audit was imminent at the time of writing.

The HTA's response to the consultation on coronial investigations of stillbirths

16. The HTA reviewed the consultation document and drafted a response, on which Members were invited to provide comment. The response, to the Ministry of Justice and Department of Health and Social Care, set out the HTA's decision not to respond to the individual questions posed within the consultation but to provide a general response about any interaction the proposed change may have with the Human Tissue Act and impact on establishments licensed within the post-mortem sector.

17. The HTA submitted its response to the consultation on the 18 June 2019 and Members will be provided with updates at a future Authority meeting. The consultation response by the Ministry of Justice is due to be published in September 2019.

Annual Business Impact Target Assessment

18. The HTA completed its Business Impact Target (BIT) Assessment for the 2018/19 reporting period in line with the statutory reporting deadline.

19. Between 21 June 2018 and 20 June 2019 there were no qualifying regulatory provisions for consideration.

20. A summary of non-qualifying regulatory provisions that arose during the reporting period will be included in the Government's annual BIT report.

Complaints

21. No complaints were received in quarter one.

HTA Strategic Risk Register
June 2019

Overview: Risks reflect the strategy for 2019 - 2022. Our highest 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 which is currently affected by recent staff changes. A number of more recently recruited Regulation Managers are now signed off to support and lead. This will increasingly have a mitigating impact on risks 1 and 4. At the beginning of June, three posts are currently vacant and are pending job evaluation. These roles of Project Manager, Data Analyst and Business Analyst are new roles dsigned to improve HTA change capabilities and aim to mitigate the risks associated with risk 6.

Other notable risks: While resources for 'no deal ' planning have been stood down, there is ongoing uncertainty posed by EU Exit meaning that resources may need to be redpeloyed at short notice later in the business year. We have appointed a Head of Planning and Performance who commences 27 August and the Head of HR was appointed and started 4 June. These roles coupled with the sign-off of more recently recruited RMs will strengthen our capability and capacity.
Progress on development activity has been slower than hoped due to staff redeployment to carry out work relating to EU exit and the opt-out consent Code but work is now underway to scope the development priorities for the coming two years in light of the funding position for the transformation programme.
DHSC spending controls are likely to place continuing pressures on ALBs to make savings.
Funding for transformation programme has not been approved for the current business year. Whilst BAU will be managed within current envelope, we recognise that pressures across the business will increase as we try to bring about essential change in 2019/20 with the same resources. This could more directly affect R1, R2, R3, R4 and R6 as the year progresses.

Risk	Mar 2019	Apr 2019	May 2019	June 2019	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 key regulatory 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. A number of new Regulation Managers recruited during the preceding year have now been signed-off to lead inspections, increasing the organisation's capacity and strengtheningour regulatory capability. A ll but one Regulation Manager post has being filled.* *The revised induction programme for RMs has been signed-off and is available to be used as a resource by all RMs and any prospective new recruits. A review of Standard Operating Procedures was recommended by the internal audit on key regulatory processes to improve to achieve consistency and improve usefulness to users. The internal audit on key regulatory processes also recommended that training in legislation should be incorporated in our RM induction process. This will be taken forward by the RM-Training, along with other continuing professional development training, including in SOPs.* *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.*
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 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 are aware that if there is a 'no deal' EU Exit, this could affect our ability to respond or regulate effectively. We feel the plans in place are adequate.*
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. Media and FOI interest has stepped up and media are running stories for longer (or running multiple articles) than would usually be the case.* *We are conscious that we have staff operating in the frontline who may be challenged about issues beyond our control, which would be heightened in a 'no-deal' EU Exit.*
4 - Failure to utilise our capabilities effectively (Delivery a-e) (Development a-d) (Deployment a, c and d)	↑	↑	↑	→	*We continue to be in a positon to use the skills of our newer recruits more fully.* *Recruitment to RM posts has been successful, but not without salary pressure. Other roles have been harder to fill as a result of salary and T&C differences with other organisations. Workload and pressure continue to be monitored closely by the management team and the actions agreed as a result of the staff survey have now been completed. We achieved our planned position relating to GDPR by the end of March 2019 and have received moderate assurance from internal audit. The additional funding available at the end of 2018/19 was used effectively. Good progress has been made on improving our induction procedures and this will be supported by the appointment of two RMs with responsibility for induction, learning and development. DHSC has introduced spending controls which could impact on future delivery.* *Related to R1, the challenge of employing the right people for the right jobs suggest that this risk has risen slightly. The recently conducted stress survey results and feedback reflect the pressure staff are under. An increase in workloads is a key factor. The response to this is being led by the CEO. Hard decisions around resourcing for the Transformation Programme will need to be made if funding is not approved by DHSC.* *Funding for Transformation Programme not approved. The result of this means that staff will ned to be redeployed to carry out work on the programme which will impact on BAU in terms of quality and pace*
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 will continue to be tight however as inflationary pressures and the non-funded portion of Employers' Pension contributions offset these gains. This pressure will become more acute if the business case to release reserves is not approved.* *Funding for Transformation programme not approved in the current business year.This does not impact on BAU activities as we will manage within the agreed budget. We do however, recognise that there will be pressures elsewhere in the business as staff are asked to take on unfunded work for the above programme.*
6 - Failure to achieve the benefits of the organisational transformation programme (Development objectives a-d)	→	→	↑	→	*This is a new risk for which we have begun to look at the outcomes and deliverables. The risk has been scored as high impact and low likelihood due to the proximity of the programme. The impact of 'high' recognises that aspects of the programme in particular IT related could have significant impact on the business should things go wrong.* *No change.* *DHSC have not agreed funding for this programme in the current business year, this will require a re-prioritisation of work to increase our capacity to take on necessary change associated with the Programme in 2019/20.*

Risks are assessed by using the grid below

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

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

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

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 May 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 September 2018
						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
						People									
						Adherence to the HTA People Strategy which has been substantially amended and approved by the Authority				X			Preventative	Management information and assessment presented to the Authority quarterly as part of the Deployment report	Quarterly report made at May 2019 Authority meeting
						Training and development of professional competence				X			Preventative	Annual PDPs, RM proposals to SMT	Regulation training plan agreed by SMT in June. Training records added onto Simply Personnel and monthly HR updates presented at SMT. End of year PDP process has commence and due to complete by end May 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									
						Use of existing regulatory model to manage the outcomes of 'no-deal'									
						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 (HL)	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***		X			Preventative	Monthly reports to HTAMG	Monthly reports on vacancies by the Head of HR to HTAMG 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 April 2018.
						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	Reviewed by ARAC October 2018
						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	Media policy to be reviewed.
						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	SO reviewed and agreed in 4 May 2017 (next review May 2019)
						Regulatory decision making framework				X			Preventative	Reports to Authority of key decisions in Delivery Report	RDMs summarised in Delivery Report to Authority Meeting in May 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 June 2018
						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
						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								Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting	EU Exit planning is a standing item on the weekly Senior Management Team Meeting and was covered in detail at both the February and May Authority Meetings.

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:* ***Hazel Lofty***	***Cause*** ***External factors*** • *No scheduled review of Human Tissue Act and associated regulations, or Quality and Safety Regulations (other than for EU Exit)* • *Rapidly advancing life sciences* • *Potential move away from the UK as base for some regulated establishments/sectors due to EU Exit and changes in exchange rates* • *Introduction of deemed consent for Organ donation in England* • *Uncertainty posed by EU Exit, and misperceptions stemming from a 'no-deal' scenario* ***Matters which certain stakeholder groups believe require review*** • *Scope of relevant material e.g. waste products* • *Licensing requirements e.g. transplantation research* • *Regulation relating to child bone marrow donors* • *Issues raised by emergence of social media e.g. non-related donors* • *Strengthening of civil sanctions for non-compliance* ***Matters which stakeholders/public may expect to be inside regulatory scope*** • *Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure* • *Police holdings* • *Products of conception and fetal remains* • *Data generated from human tissue* • *Funeral directors* • *Forensic research facilities* • *Cryonics* • *Body stores / Taphonomy* • *Imported material* • *Clinical waste* • ***Other*** • *Inadequate stakeholder management* ***Effect*** • *Diminished professional confidence in the adequacy of the legislation* • *Reduced public confidence in regulation of matters relating to human tissue*	*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 March 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 2018* *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*
						Clear view of use of s.15 duty to report issues directly to Ministers				*X*			*Preventative*	*Duty and its uses understood by SMT and Chair*	*Letter to Minister re. import and consent requirements for public*
						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*
									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*

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
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:* ***Allan Marriott-Smith***	• ***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*	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 action plan largely complete at end March 2019. 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. Monthly operational cyber risk assessments. Annual SIRO report	Annual SIRO report presented to ARAC June 2018
									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 actiivity 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		1 X	2 X	3	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 January 2019 meeting
						Rigorous debt recovery procedure				X			Preventative	Monthly finance reports to SMT and quarterly to Authority	Last quarterly report May 2019
						Reserves policy and levels reserves				X			Monitoring	Reserves policy reviewed annually and agreed by ARAC	Last agreed by ARAC October 2018
						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 December 2018
						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 2018.
						Annual external audit						X	Detective	NAO report annually	Last report in June 2018 - 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 April 2019
									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 and CQC maintain contact over common issues 2019/20
									Action plan to move from rudimentary to Basic level of maturity on the GovS 013 Functional Standards	X	X		Preventative		

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							4	4							
6	***Failure to achieve the benefits of the organisational transformation programme*** ***(Development objectives a-d)***	***Causes*** • *Uncertainty of funding* • *Programme and project benefits poorly defined and understood* • *Inadequate programme and project governance arrangements* • *Poorly specified programme and projects* • *Insufficient programme, project and change management skills* • *Inadequate leadership of change* • *Inability to access the necessary skills required at a affordable cost* • *Lack of staff buy-in to change* • *Management and Head stretch of delivering transformation alongside business as usual and other development activity* • *Insufficient agility in (re)deploying people to change projects* • *Poorly specified procurement and inadequate contract management* • *Realisation of single points of failure for DDAT and People Strategy* ***Effects*** • *Wasted public money* • *Failure to achieve the central strategic intent of the Authority* • *Distracts senior management from operations at a time when demands have increased* • *Reputational damage* • *Unaffordable cost over run* • *Staff demotivation* • *Data remains under-utilised* • *Technology inadequate to meet future needs (cost, functionality)* • *Limited ability to achieve improvements in efficiency and effectiveness* • *Pace of change is inadequate and impacts negatively on other work*	5	4		SMT experience of organisational change, programme and project management				X			Preventative		
						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		
						Agreement to a phased delivery approach to avoid all or nothing investment and align with availabile funding				X			Preventative		
						Obtain external advice on programme design and implementation			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		

Authority Report

Delivery – Quarter 1 2019/20

Date	18 July 2019	**Paper Reference**	HTA (17/19)
Agenda Item	8	**Author**	Nicolette Harrison
Protective Marking	OFFICIAL	**Author Contact** Nicolette.harrison@hta.gov.uk	
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. Report provided to the Authority annually (Q2) on the outcomes of our regulatory interventions and the impact on patient safety and public confidence 3. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly) (see page 7, paragraph 34). 4. 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) [See KPI narrative on page 12] 5. 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) 6. 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)		

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 16a/19 for detailed information)**

Purpose of paper

1. To provide the Authority 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, including statistics and background information set out in **Annex A**. **Annex B** reports Serious Adverse Events and Adverse Reactions (SAEARs) HTA Reportable Incidents (HTARIs).

Decision-making to date

3. This report was approved by the CEO on 4 July 2019.

Action required

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

Director's summary

5. The Authority will note from the various data and summaries provided in this report that it has been a very busy start to the new business year across all areas of operational activity, from the harder end of the spectrum of regulatory intervention, such as suspension of licences, to the softer end with our extensive communication activity.

6. Having slightly reduced the target for numbers of site visits this year compared with previous years (180 down from 200), the number achieved in this first quarter is greater than might be expected if these were spread evenly over the course of the year. We are planning a reduced rate of inspections over the summer and later in the year to free-up resource for other business priorities, which should also balance site visit numbers against the target.

7. The Authority should also note that whilst site visits mostly comprise scheduled inspections to hubs and satellites, they also include Licence Application Assessment Visits (LAAV), Corrective and Preventative Action (CAPA) follow-up visits (to gain assurance in the most serious cases) any other non-routine visits.

8. In addition to a high level of scheduled or routine activity, such as site visits, licence applications and variations and enquiries, we have experienced a particularly large volume of urgent and high priority demand-led work. These have included urgent approvals, Regulatory Decision Meetings and legal notices mostly arising from the use of new and innovative processes by those we regulate or investigation of potential regulatory breaches. Brief summaries of these more formal regulatory actions are given under the relevant sections of this report.

9. Despite these pressures, it is pleasing to note that key performance indicators for regulatory delivery have largely remained on track, although there were some exceptions in KPI 4 (which is not RAG-rated) as detailed later in this report.

10. The communications section of this report gives an illustration of the wide range and depth of our activities, including our increasing use of digital communication channels. I was pleased to be the first contributor to our new blog capability and to report that we have a healthy pipeline of further (no doubt more technical) blogs, to be published at regular intervals. This communications activity is vital in enabling us to efficiently and effectively extend our reach to the public and the communities whom we regulate.

11. The annexed data gives more depth to supplement the summaries in this narrative section of the report. It is worth noting that the increase in post-mortem sector incidents closed is a reflection of a strong focus from that team, supported by the development of a dashboard using data from our case management system. Open incidents, especially older ones, have been critically reviewed and actively followed up to obtain and review relevant information from the establishments to enable decisions to be made about whether those incidents could be closed, or if further action were needed. This is a tangible example of how datasets originally developed for the Safety KPI work are being operationalised to improve our regulatory approach.

Critical shortfalls

12. There were no critical shortfalls during quarter one.

Investigations

New investigations

13. There was one new investigation in quarter one.

Investigation 06/18

14. The HTA has undertaken an investigation into exhibitions of human bodies and tissues that were advertised as being due to take place in June and July 2019, on premises that are not licensed by the HTA. The HTA advised the organiser and the venues that, based on the information provided to us, the events would need to be on HTA-licensed premises. The organiser informed the HTA that the events have been cancelled. The organiser stated that they plan to undertake the events in future and that they will contact the HTA to discuss the licensing requirements prior to any event taking place.

Update on investigation reported in previous Delivery report (HTA 11/19)

Investigation 04/18

15. The HTA is continuing to investigate case 04/18 and is in the process of contacting establishment(s) affected by the activity in question. Through the course of the HTA's enquiries, it has come to light that a second company, with apparent links to first, may also have conducted licensable activities without a licence; the initial investigation has therefore been expanded to include this company and any licensable activities it may have been involved in.

Non-routine site visit inspections

16. There were no non-routine site visit inspections in quarter one.

Police referrals

17. SMT did not consider any potential breaches of human tissue legislation during quarter one.

Legal notices

18. We issued one set of Directions in quarter one. The directions were issued to an establishment in the Human Application sector (see RDM one and two, below).

Regulatory decision meetings

19. Eleven regulatory decision meetings (RDMs) and one Case Review Meeting (CRM) were held in quarter one.

RDM one and two

20. Two RDMs were held to discuss concerns about an establishment in the Human Application sector. The DI had indicated that samples would be transferred to another establishment and the licence revoked. The DI and PD left the company. It was unclear whether there was anyone taking responsibility for the oversight of the samples being stored on the premises. The first RDM resulted in Directions being issued for the establishment to transfer the samples to another licensed establishment; however, this was not completed by the imposed deadline, and therefore a second RDM was convened, which led to a number of actions being taken to ensure that the samples be transferred to another establishment as swiftly as possible. The samples have since been transferred and the establishment has revoked its HTA licence.

RDM three

21. An establishment in the HA sector had not notified the HTA of a change in premises. The establishment was not forthcoming in providing the requested information, and the RDM agreed that the licence should be suspended until further notice. The suitability of the DI was also considered as there was concern that the DI had not been proactive in informing the HTA of significant changes to the licence.

RDM four and five

22. An RDM was convened to review the response from an organisation which, in the past, potentially acted outside of the licensing framework. At the meeting, a decision to seek further information regarding the distribution of tissue from source to end user was taken. A second RDM was held a month later, where a decision was made to contact the end users of the tissue to alert them to the fact that it may have been supplied outside of the required licensing framework and to advise them to risk assess its use.

RDM six

23. An establishment submitted a preparation process dossier (PPD) to the HTA. After approval to undertake the validation study, a report was provided. The report did not meet the pre-defined acceptance criteria and did not justify the changed criteria. As a

result, the HTA was unable to provide an authorisation for the PPD without submission of additional data and clarification of issues identified with the report. However, the establishment scheduled patients for surgical procedures and the RDM was convened to discuss the situation and submitted PPD, and to agree next steps. It was agreed to request missing data and clarification of issues with the validation report.

RDM seven

24. An establishment licensed in the Human Application sector was found to have procured a new tissue type without prior notification to the HTA. The RDM considered the circumstances of this case, the action taken by the establishment to investigate the matter, and the steps they have taken to prevent a recurrence. The RDM concluded that further assurances should be sought on a number of points, but that no further regulatory action was needed at this time.

RDM eight

25. In autumn 2018, a PPD was submitted by an establishment to vary an existing processing activity. During a subsequent routine inspection, it was determined that the process, yet to be authorised, has been undertaken by the establishment on a number of occasions. The HTA also understands that the establishment has undertaken procurement activities under the authority of their licence in relation to this activity, without prior notification to the HTA. An RDM was held to consider the circumstances of this case, and concluded that further assurances were required on a number of points. This will be sought from the establishment and a further meeting convened to consider the information provided.

RDM nine

26. An RDM was convened to consider whether to reissue Notices of Suspension to two organisations in the HA sector that went into administration last year. The HTA determined that the licences should continue to be suspended.

RDM ten

27. An establishment was found to have been storing tissues for human application outside of the licensing framework in place and without the DI's knowledge. A decision was made to request further clarifications from the establishment as to the circumstances, and make a decision on further actions once this information is available.

RDM eleven

28. An RDM was convened to discuss an establishment in the Human Application sector which was found to have been processing tissue without authorisation from the HTA, and exporting material for human application without a licence. It was decided that the exporting of material without a licence will be put to HTA SMT for a decision on whether

or not to refer the matter to the police. With regards to the processing of tissue without authorisation from the HTA, further information about the case will be sought and a decision on any further actions will be made at a future RDM.

CRM one

29. The CRM was convened to discuss findings from a routine inspection of an establishment in the Post-Mortem sector. The inspection found a number of shortfalls in areas where shortfalls had been raised during previous inspections of the establishment, and some tissue samples were found to be stored without appropriate consent. It was agreed that none of the shortfalls were critical in nature, and that the CAPA process is appropriate for managing the shortfalls identified. It was also agreed that the DI continues to be suitable.

Reconsiderations, representations and appeals

30. No reconsiderations, representations or appeals were considered during quarter one.

Other regulatory activity

31. In relation to investigation 06/18, the HTA issued five notices to advise the organisations involved not to undertake licensable activities on unlicensed premises.

Enquiries

General enquiries

32. During quarter one, we recorded 581 general enquiries, compared with 639 in the previous quarter. The enquiries included:

    a. 298 from members of the public about body donation (150 were received via email or phone, and in the post, and 148 via the website). This compares to 205 in the previous quarter.
    b. 283 from professionals about licensing or other areas of our regulatory work, compared with 434 in the previous quarter.

33. Of these enquiries, 335 were received via the website, compared with 323 last quarter. Other enquiries are usually received by phone.

34. The HTA sets itself a KPI of responding to 95 percent of general enquiries in ten working days. Of enquiries received during quarter one, 95* percent were closed in our case management system within ten working days, 96 percent in the previous quarter. Over quarter one, 98 percent of enquiries were responded to within twenty working

days, with the average time taken in quarter one standing at five. The cases that fell outside ten working days generally tended to involve either more complex multi-agency enquiries, or concerns raised with us about establishments.

** This figure for the KPI is indicative only due to the time of the month the data is being collected.*

Freedom of Information Act (FOIA) requests

35. We had three requests in quarter one, compared with 15 in the previous quarter 4. We publish FOIA responses on our website.

Stakeholder engagement

EODD planning

36. On the 12 October 2019, London will be hosting the 20th European Day for Organ Donation and Transplantation (EODD).

37. The main objectives of EODD are to raise public awareness and establish trust among the general public, to engage policy-makers and the medical community, and to encourage public debate and provide information so that each person can decide on donation and make their wishes known to their family.

38. In April, the HTA participated in a teleconference to advise on preliminary planning for the series of events that will be steered by NHSBT and the European Directorate for the Quality of Medicines (EDQM) to mark the day.

Dying Matters Awareness Week

39. This year, Dying Matters Awareness Week took place between 13-19 May. The theme this year was based on the question - '*Are We Ready*?'

40. To support the week and its theme, the HTA undertook a series of engagement activities to raise awareness. Through our website and social media channels, we encouraged people to have conversations with loved ones about donation arrangements after death.

41. On the 16 May, we held a webinar for members of the public explaining our regulation of the post-mortem sector, which included information on how we ensure that mortuaries meet our standards, and that support is available for those who are bereaved and are affected by a post mortem examination. It also covered information

on body, tissue, and organ donation.

42. We received very positive feedback on the webinar, which had approximately 20 participants. We also made a recording of the presentation available on our YouTube channel for those who were not able to join us live.

HTA blog

43. At the end of May, the HTA launched a new blog platform, to coincide with the circulation of the May professional eNewsletter.

44. Members will recall that the blog was developed with input from the HTA Licensed Establishment Relationship Programme (LEEP) group. It has been agreed that the HTA will post a blog on a monthly basis.

45. To support those volunteering to write a blog for the HTA, we have developed guidance and tips to outline considerations, such as tone and format, when writing an HTA blog. We have also produced some community guidelines for people who comment below the line, in order to make it clear what we wouldn't publish (e.g. any offensive or defamatory material); the community guidelines can be found on the HTA blog page.

46. The first blog was submitted by Nicky Harrison who shared her thoughts on the HTA's role and how we came about. The second blog was published at the end of June and was written by Andy Hall on key considerations when setting up a biobank.

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

Wales Transplantation Advisory Group (WTAG)

48. The HTA attended a WTAG meeting in June. The key points and items raised at this meeting included:

    a. Welsh Government's organ donation communications plan update.
    b. Updates on the DHSC consultation on excluded material in England.
    c. Future updates to the Welsh Code of Practice in relation to opt-out changes in England
    d. Deemed consent in England
    e. EU exit preparations
    f. Updates from each Welsh health board on challenges and successes over the past year.

Anatomy compliance updates report

49. In May, we published a report summarising the findings from the 2017 round of compliance updates for the Anatomy sector.

50. The report was shared via the May professional newsletter and it was made available on the HTA website. The report reflects that Anatomy sector compliance updates showed high levels of good practice.

51. This corresponds with the low levels of shortfalls identified during the inspection of Anatomy establishments, and our intelligence that tells us there is a widely-held respect for the gift of body donation and a genuine commitment to uphold the dignity of the deceased.

Engagement with the public review panel

52. Members will recall that the HTA has a public review panel that we occasionally contact to seek their feedback on our work.

53. In quarter one, we sought feedback from the public panel on our body donor cards; these are card that we issue to potential body donors who request a printed copy of the HTA body, brain, and tissue donation pack.

54. We first launched the cards in 2016, following a suggestion from a member of the public, and since their initial development, we have not explored whether or not the public find them useful.

55. To gain a better understanding of the benefit of the cards, we surveyed the public panel to seek their views.

56. We received a total of 51 survey responses:

    a. 96% of respondents stated that they would find the cards useful.

    b. Only 20% of respondents knew that the HTA offered body donor cards, yet the majority of respondents said that they were either very inclined or inclined to carry it on their person.

    c. We received several comments on the survey asking us to increase public awareness about the existence of the cards.

57. In an effort to respond to these suggestions, the HTA will be working on template body donor cards based on the HTA version. These templates can be downloaded from the website and individually branded by medical schools, so that they can issue them to body donors, along with consent forms. We expect these will be available on the HTA website during quarter two.

58. The HTA also promoted our own branded body donor cards through social media and via the public newsletter.

59. In June, we also contacted members of the public panel to help promote the HRA's consultation called '*Make It Public*', which seeks views on research transparency.

Stakeholder and Fees Group meeting

60. In May, we held the eleventh Stakeholder and Fees Group advisory meeting. More information on discussion held at the meeting can be found in the HTA paper 20/19 (agenda item 11).

Engagement with licensed establishments

61. We published professional newsletters in May of quarter one (details are below in the Digital Communications section).

62. Through LEEP, the HTA continues to monitor and promote engagement with the HTA online tests. As of quarter one, the tests have been taken over 2000 times since their launch in March.

63. We have received excellent feedback from licensed establishments on these tests.

Delivery KPI narrative

Performance against 2019/20 KPIs

64. As agreed with the Authority, KPI 4 is not allocated a RAG rating.

65. In April, four out of nine major and critical shortfalls (eight major, one critical) were assessed within the required timeframe following submission of evidence. Of the other five, two major shortfalls have since been closed down within the required timeframe (following delayed submission of evidence); one major shortfall closed as the company's licence has since been revoked; one major shortfall extended (following a change of licensee staff) to a mutually agreed future date; and one critical shortfall continues to remain open as the DI has yet to provide sufficient evidence for us to assess.

66. In May, all nine major and critical shortfalls (all major shortfalls) were assessed within the required timeframe following submission of evidence (which was submitted beyond the deadline in all instances)

67. In June, eight out of nine major and critical shortfalls (all majors) were assessed within the required timeframe following submission of evidence (which was submitted on time in 50% of cases). One shortfall remained open at the time of report compilation due to temporary staff illness.

68. In June, KPI 7 was not met. 43 cases were referred to panel for approval, several of which required a decision in less than 10 working days. As a result, a decision was not made on two out of 43 cases within 10 working days. Both cases were resolved within 12 working days.

69. All other Delivery KPIs for quarter one were within target or tolerance.

Annex A – Statistics and background information

Regulation

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

Type of site visit	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Routine inspection	40	39	41	37	157	150	136
LAAV – new application	4	1	3	3	9	11	18
LAAV – variation	0	0	0	1	2	0	1
Satellite site inspection	20	11	16	8	49	66	46
CAPA follow up	4	1	1	3	6	5	1
Non-routine inspection	0	0	0	0	0	4	1
Total sites visited	**68**	**52**	**61**	**52**	**223**	**236**	**203**

Table Two: Closed HTARIs in the post-mortem sector

70. In 2016/17, mortuaries licensed by the HTA admitted around 334,000 bodies, and performed over 90,000 post-mortem examinations. In this context, the number of reported HTARIs is very low.

71. The table below describes the number of HTARIs that were closed in each period. This does not include any incidents that were, on investigation, found not to fit the criteria of a HTARI. Further detail on each case can be found in Annex B.

72. These numbers may vary from previous reports due to incidents being re-opened for further information to be added, and then closed in a different quarter or financial year.

HTARI Classification	**Q1 2019 /20**	**Q4 2018 /19**	**Q3 2018 /19**	**Q2 2018 /19**	**2018/19 Total Year**	**2017/18 Total Year**	**2016/17 Total Year**
Accidental damage to a body	9	14	12	9	47	48	33
Discovery of an additional organ(s) in a body on evisceration for a second post- mortem examination	0	0	0	0	0	0	0
Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	1	0	0	0	0	2	0
Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	8	4	1	2	8	4	7
Disposal or retention of an organ against the express wishes of the family	0	1	0	0	1	5	0
Discovery of an organ or tissue following post-mortem examination and release of body	2	5	2	0	8	9	4
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	0	1	0	0	1	1	1
Loss of an organ	2	0	1	0	2	6	0
Major equipment failure	3	1	0	0	4	8	8

HTARI Classification	Q1 2019 /20	Q4 2018 /19	Q3 2018 /19	Q2 2018 /19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	1	0	0	1	2	2	1
Post-mortem examination of the wrong body	0	0	1	3	4	3	2
Release of the wrong body	5	0	4	2	10	15	9
Removal of tissue from a body without authorisation or consent	0	0	4	2	6	1	2
Serious security breach	4	0	5	3	10	8	1
Viewing of the wrong body	1	0	2	1	5	9	9
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	12	5	10	12	38	28	12
Total	**48**	**31**	**42**	**35**	**146**	**149**	**89**

Table Two B: Reported HTARIs in the post-mortem sector

73. This table shows all incidents reported to the HTA as HTARIs. This also includes any near misses and incidents that may, on investigation, be found not to be reportable incidents.

	Q1 2019 /20	Q4 2018 /19	Q3 2018 /19	Q2 2018 /19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Number of reported HTARIs	44	64	35	47	205	230	160

Table Three: Closed SAEARs in the human application sector

74. 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.

75. The table below describes the number of SAEARs that were closed in each period. This does not include any incidents that were, on investigation, found not to fit the criteria of a SAEAR. Further detail on each case can be found in Annex B.

76. These numbers may vary from previous reports due to incidents being re-opened for further information to be added, and then closed in a different quarter or financial year.

Type of Event or Reaction	**Q1 2019/20**	**Q4 2018/19**	**Q3 2018/19**	**Q2 2018/19**	**2018/19 Total Year**	**2017/18 Total Year**	**2016/17 Total Year**
Event linked to Distribution	0	2	1	2	5	1	6
Event linked to End use	0	0	0	0	0	0	0
Event linked to Materials	1	0	0	0	0	1	2
Event linked to Preservation	0	0	0	0	0	0	4
Event linked to Processing	10	7	4	2	20	21	13
Event linked to Procurement	19	13	9	4	40	18	11
Event linked to Storage	4	2	1	0	4	10	10
Event linked to Testing	4	3	3	1	12	6	0
Event linked to Transportation	0	2	1	0	4	2	2
Event linked to Other process	4	2	1	0	5	8	4
Total – Events	**42**	**31**	**20**	**9**	**90**	**67**	**52**
Reaction in Donor	0	0	0	0	0	2	0
Reaction in Recipient	0	0	0	1	3	10	8
Total – Reactions	**0**	**0**	**0**	**1**	**3**	**12**	**8**
Total – Events and Reactions	**42**	**31**	**20**	**10**	**93**	**79**	**60**

Table Three B: Reported SAEARs in the human application sector

77. This table shows all incidents reported to the HTA as SAEARs. This also includes any near misses and incidents that may, on investigation, be found not to fit the criteria of a SAEAR.

	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Number of reported SAEs	73	67	65	63	279	157	83
Number of reported SARs	7	13	13	11	44	27	24
Total	**80**	**80**	**78**	**74**	**323**	**184**	**107**

Table Four: Closed SAEARs in the Organ Donation and Transplantation sector

78. During 2018/19, a total of 5090 organ transplants, from 1574 deceased and 1051 living donors, were carried out in the UK (England, Wales, Northern Ireland and Scotland).

79. The table below describes the number of ODT SAEARs that were closed in each period. This does not include any incidents that were, on investigation, found not to fit the criteria of an ODT SAEAR. Further detail on each case can be found in Annex B.

80. These numbers may vary from previous reports due to incidents being re-opened for further information to be added, and then closed in a different quarter or financial year.

Type of Event or Reaction	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Events	10	9	6	3	20	29	28
Reaction in Donor	1	0	0	0	0	1	0
Reaction in Recipient	13	7	1	7	20	17	18
Total	**24**	**16**	**7**	**10**	**40**	**47**	**46**

Table Four B: Reported SAEARs in the Organ Donation and Transplantation sector

81. This table shows all incidents reported to the HTA as ODT SAEARs by NHSBT. This also includes any incidents that were, on investigation, found not to fit the criteria of an ODT SAEAR.

	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Number of reported ODT SAEs	19	12	13	2	33	22	38
Number of reported ODT SARs	12	8	10	2	29	15	26
Total	**31**	**20**	**23**	**4**	**62**	**37**	**64**

Table Five: Bone marrow and PBSC cases where the donor lacks capacity/competence

	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year	2017/18 Total Year
Approvals	15	24	17	17	71	22

Table Six: Living organ donation cases

			Type of case								TOTALS		
Q1	Directed kidney		Directed altruistic kidney		Non-directed altruistic kidney	Paired or pooled kidney	Directed liver lobe		Non-directed altruistic liver lobe	Directed small bowel	Number of cases considered	Approvals by the Living Donation Assessment Team	Approvals by Authority panels
	LDAT	**Panel**	**LDAT**	**Panel**	**Panel**	**Panel**	**LDAT**	**Panel**	**Panel**	**LDAT**			
Q1 19/20	196	4	2	0	22	55	10	0	0	-	289*	208	81
Q4 18/19	204	0	3	0	29	51	6	0	1	-	294*	213	81
Q3 18/19	222	0	2	0	27	66	9	0	1	-	327	233	94
Q2 18/19	226	0	2	1	19	42	11	0	1	1	303*	240	63
18/19 Total Year	**863**	**1**	**12**	**2**	**95**	**4**	**30**	**0**	**4**	**1**	**1228**	**906**	**322**
17/18 Total Year	**855**	**1**	**6**	**5**	**98**	**12**	**36**	**0**	**12**	**-**	**1214**	**897**	**317**

* Number of cases considered using the emergency out-of-hours process. Q1 (19/20) and Q4 (18/19) includes one case each and Q2 (18/19) includes two cases.

Communications

Social media

82. In quarter one, the HTA's Twitter account had 2,236 followers, up from 2,162 in the previous quarter. Our engagement rate increased to 1.4% from 1.2% during the previous quarter, with a peak rate of 5.4%.

83. On average, HTA tweets were seen by 1,531 people per day, an increase from 700 per day in the previous quarter. Our impression rate this quarter was 1,480 impressions per tweet. This has increased from 1,140 impressions per tweet in the previous quarter.

Table Seven:

Month	Impressions	Profile Visits
April	28.7K	1,304
May	52.6K	1,507
June	58.5K	1,661

84. Tweets with the highest reach and engagement in quarter one were about:

a. Corporate
Promoting our website quizzes for professionals.
https://twitter.com/HTA_UK/status/1113775435253518336

b. Organ donation and transplantation
NHSBT's video on deemed consent.
https://twitter.com/HTA_UK/status/1121728898184679425

c. Dying matters
Launch of our Dying Matters awareness week campaign in May.
https://twitter.com/HTA_UK/status/1127884967177011200

d. Blog
Launch of our new blogging platform.
https://twitter.com/HTA_UK/status/1134056888738439170

e. Deceased donation
Information on how to donate your body to a medical school after death.
https://twitter.com/HTA_UK/status/1128638772176924673

f. Research
Promoting a webpage that contains our information on donated tissue and how it's used in research. https://twitter.com/HTA_UK/status/1133743590419468288

g. Authority
Authority meeting in May https://twitter.com/HTA_UK/status/1126414154569482240

85. There are 901 Facebook 'likes' on the HTA page, up from 868 in the last quarter. The HTA also had 661 followers for its LinkedIn company page, up from 631 in the previous quarter.

Digital communications and publications

Table Nine: Digital users

	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year
Users	51,388	87,437	78,090	70,938	218,196
Page views	228,891	336,543	288,025	271,911	823,214
Pages viewed per session	3.16	2.22	2.17	2.25	2.29
Average session duration	00:02:42	00:01:41	00:01:42	00:01:40	00:01:60
Online enquiries	399	323	358	334	1,029
eNewsletter signups	240	170	125	475	1031

86. The highest viewed pages are:

Table 10: Page views

Highest viewed pages	Q1 2019/20	Q4 2018/19	Q3 2018/19	Q2 2018/19	2018/19 Total Year[1]
Body donation FAQs	1,667	4,446	5,633	6,562	23,056
Medical school search	10,862	13,179	12,925	14,129	53,756
Donating your body info	20,307	24,634	23,457	25,802	101,630
Guidance for professionals	5,684	6,082	4,899	4,338	20,013

87. The most frequently clicked top menu items on the front page are:

    a. Guidance for professionals – 5021 clicks;
    b. Guidance for the public – 2057 clicks; and
    c. About us – 1886 clicks.

Newsletters

88. The HTA sent out a professional newsletter in May and an Independent Assessor bulletin in May. The HTA public newsletter was sent out in June and May.

89. There was a significant drop in distribution numbers for the professional newsletter as we cleaned out distribution lists to remove anyone who had voluntarily signed up for the newsletter but had not opened any of the previous five editions. Our licence contacts who had not opened recent versions were **not** removed.

90. The government average is for 24% of subscribers to open newsletters.

Table 11: Professional newsletter

Month	**Recipients**	**Open rate**
July 2018	4,380	34%
September 2018	4,469	18%
December 2019	5,795	31%
January 2019	4,564	47.8%
March 2019	4,873	31.5%
July 2019	3,076	28%

Table 12: Independent Assessor bulletin

Month	**Recipients**	**Open rate**
November 2017	272	35%
January 2018	268	44%
July 2018	266	36%
October 2018	265	37%
January 2019	265	37.5%
May 2019	263	28.9%

Table 13: Public newsletter

Month	Recipients	Open rate
February 2018	1,249	40%
June 2018	1,371	49%
August 2018	1,371	45%
December 2018	1,606	41%
February 2019	1,837	39%
June 2019	1,747	32.2%

Media coverage

91. During quarter one, coverage which directly mentioned the HTA included:

a. Coverage of HTARIs following an FOI request, including a statement and quote from the HTA:

i. Shock at morgue errors as families shown wrong bodies and foetus remains 'incinerated' without parents' knowledge (Telegraph)

ii. Dead patient's body damaged at Worcestershire Royal Hospital (Worcester news)

b. Father's body exhumed in hope of clearing son of Tyneside rapes (BBC News)
The body of a jailed double rapist's father has been exhumed in an effort to prove the son's innocence. Contains a statement from the HTA about DNA testing under the HT Act.

c. UK to open first 'body farm' for forensic research (Nature)
This article reports that forensic scientists are working with the British military to open the UK's first body farm. It also refers to a recently published response to an FOI request, and features an HTA statement.

d. 'Yuck factor' puts off eye donors, leaving vital transplants at risk (Guardian)
An article exploring the 'yuck factor', suggests that because eyes are on the outside of the body, people feel more attached to them. This is explained as a reason for the shortage of eye donors. The article then goes on to say that in the event a no-deal Brexit, hospitals will need a licence from the HTA to import corneas from the EU (details on licensing requirements were provided by the HTA)

e. Coverage of cord blood banking following an FOI release from the HTA:

i. Cord blood: Rise in parents paying for private banking (BBC News)

ii. Number of Brits paying to freeze their baby's stem-cell-rich umbilical cord in hope of curing them of crippling conditions in the future has risen by 60% in four years, figures show (Daily Mail)

iii. Umbilical Cord Blood Banking On The Rise In UK – Here's What You Need To Know (Huffington Post)

iv. Why are parents paying thousands to freeze their babies' umbilical cords? (Yahoo News)

Annex B – SAEARs / HTARI details

Human Application – Serious Adverse Events

Case Number	Process Event Linked To	Description of Event
CAS-45457-K2G3	Procurement	Contamination of stem cells
CAS-41519-H7Y9	Procurement	Microbial contamination of bone marrow
CAS-43052-V1Y2	Procurement	Sterility check post procurement was positive
CAS-44113-J6V0	Testing	Possible contamination of stem cells
CAS-45698-H8H3	Testing	Initial positive sterility result
CAS-46367-G9L5	Procurement	Initial sterility check was positive
CAS-48322-G4P0	Procurement	Initial sterility test by collection centre was positive
CAS-47739-N2X4	Procurement	Positive microbiology test result on procured unit
CAS-47740-P4D4	Procurement	Positive microbiology test result post procurement
CAS-48459-X1H1	Procurement	Positive microbiology test result post-processing
CAS-43855-H9B8	Processing	Positive microbiology test result after issue of tissue
CAS-47398-V2K4	Procurement	Tissue unsuitable due to packing error
CAS-44507-P0S1	Processing	Positive microbiology test result post-processing
CAS-46127-B8S1	Processing	Positive microbiology test result post-processing

CAS-47658-V3J3	Procurement	Positive microbiology test result on procured unit
CAS-46125-G6V1	Processing	Positive microbiology test result post-processing
CAS-43859-T5W1	Processing	Incorrect formulation of reagent supplied by a third-party supplier
CAS-40181-D2M8	Processing	Loss of tissue due to contamination by a foreign object
CAS-41677-K3Q7	Other	Inappropriate release of tissue not all acceptance criteria met
CAS-43436-F5K9	Processing	Positive microbiology test result post-processing
CAS-43947-G7L1	Procurement	Positive microbiology test result post-processing
CAS-44121-R6P1	Testing	Positive microbiology test result on procured unit
CAS-44167-F8P7	Procurement	Positive microbiology test result on procured unit
CAS-45574-V4C8	Processing	Positive microbiology test result post-processing
CAS-46613-D1P6	Processing	Patient developed side effects which may have been due to a combination of stem cell infusion and medication
CAS-48306-C3S2	Other	Treatment for possible donor acquired infection may have contributed to failure engraft
CAS-48403-Y4H2	Procurement	Sterility check pre and post-processing was positive
CAS-49166-P6T0	Materials	Cancellation of a planned procedure because incorrectly assumed that correct type of tissue had been received into storage
CAS-47748-X9X3	Testing	Mandatory serology testing procedure not followed
CAS-48492-M0H3	Other	Initial sterility result was positive
CAS-43474-S4J2	Procurement	Tissue product contamination during harvest.

CAS-43921-B9V9	Procurement	Tissue product contamination during harvest
CAS-43930-V2H0	Procurement	Tissue product contamination during harvest
CAS-48067-G0S8	Procurement	Sterility check post-procurement was positive
CAS-44881-L8C6	Processing	Possible contamination of cord blood unit
CAS-47848-P7B9	Procurement	Contamination of allogenic bone marrow unit
CAS-49921-V0S6	Procurement	Positive sterility on procured unit.
CAS-43806-D5W4	Storage	Use of tissues past expiry date
CAS-43807-Q6Z7	Storage	Use of tissues past expiry date
CAS-43808-S8Y8	Storage	Use of tissues past expiry date
CAS-48270-W8H1	Other	Leakage of stem cells.

Human Application – Serious Adverse Reactions

Case Number	Donor or Recipient	Description of Event
CAS-46602-J8L1	Recipient	Patient developed side effects which may have been due to a combination of stem cell infusion and medication

Organ Donation and Transplantation – Serious Adverse Events

Case Number	Brief description of incident
CAS-48782-B7L6	Damage to organ - not transplantable
CAS-48799-W2W6	Damage to organ - organ sent for research
CAS-48807-B5Y9	Probable donor derived malignancy
CAS-49276-N4J4	Potential for donor derived disease
CAS-48783-S8P1	Unexpected finding post transplant
CAS-49180-C9T2	Damage to organ - not transplanted
CAS-48939-F7P9	Damage to organ - not transplanted

CAS-49072-Y5T8	Damage to organ - kidney sent for research
CAS-49413-T1H5	Finding post transplant
CAS-49503-H5C8	Living donation - finding in donor - long chain did not proceed

Organ Donation and Transplantation – Serious Adverse Reactions

Case Number	Donor or Recipient	Brief description of Reaction
CAS-48025-Q4T7	Recipient	QUOD biopsy - complication developed in recipient
CAS-44467-B1P5	Recipient	Possible donor derived illness
CAS-44468-B1Y6	Recipient	Possible donor derived illness
CAS-48221-M3Q8	Recipient	Possible donor derived illness
CAS-48811-H0Z6	Recipient	Probable donor derived malignancy
CAS-47763-H3C8	Recipient	QUOD biopsy site bleed - recipient impacted
CAS-48953-F4J5	Recipient	Recipient anaesthetised - did not receive a transplant
CAS-43958-G8H0	Recipient	Damage to organ - recipient impacted
CAS-49277-F8X3	Recipient	Potential for donor derived disease

CAS-49182-K4P7	Recipient	Recipient anaesthetised - did not receive a transplant
CAS-47831-Y2F1	Recipient	Recipient anaesthetised - did not receive a transplant
CAS-49799-H7X1	Recipient	Transplantation did not proceed - recipient impacted
CAS-49837-S0J9	Recipient	Increased recipient anaesthetic
CAS-49510-V6T6	Donor	Living donation - finding in donor - donation did not proceed

Post Mortem HTA Reportable Incidents

Case Number	Incident Classification	Brief summary of HTARI
CAS-42583-S1Z2	Serious security breach	Unauthorised persons accessed mortuary and body store.
CAS-43297-T5M1	Discovery of an organ or tissue following post-mortem examination and release of body	Administrative error led to inadvertent retention of blocks and slides.
CAS-43361-G8R4	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
CAS-43394-D9T6	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Failure of staff to follow the establishment's procedure for transfer of bodies.
CAS-43866-L2N7	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to loss of traceability of pregnancy remains.
CAS-44191-B7M1	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to a delay in disposal of fetal remains.
CAS-44226-X9Q5	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to retention of pregnancy remains rather than being returned to the family.

CAS-44496-R3R0	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-44628-V9C2	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to disposal of pregnancy remains, rather than being returned to the family.
CAS-44924-L3Y9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
CAS-44926-S4R5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Loss of valuables from the mortuary premises.
CAS-45109-W0P3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to the delay in sensitive disposal of pregnancy remains.
CAS-46139-F7L3	Major equipment failure	Freezer failure led to transfer of bodies to a temporary freezer unit
CAS-46680-G5G4	Accidental damage to a body	Human error led to accidental damage to body.
CAS-46697-T0G4	Major equipment failure	Major equipment failure led to temporary impact on establishment to store bodies.
CAS-46876-P6V4	Discovery of an organ or tissue following post-mortem examination and release of body	Discovery of organ after the release of a body.
CAS-47760-J0R5	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to disposal of a fetus by a method not in accordance with the family's wishes.
CAS-47799-B5J7	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Adverse publicity resulted from alleged theft of valuables.
CAS-47875-Z9C9	Loss of an organ	Procedural error led to loss of tissue.
CAS-47911-L4D2	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to loss of tissue.
CAS-47944-B9Y2	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-47977-X9W0	Release of the wrong body	Human error led to the release of the wrong body.
CAS-48039-W9N7	Serious security breach	Human error led to a security breach.

CAS-48065-G7F3	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-48089-Z0S3	Accidental damage to a body	Human error led to accidental damage to body.
CAS-48091-Y7X5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	The Hospital received a complaint from a family about the condition of the deceased.
CAS-48172-P8M7	Loss of an organ	Human error led to loss of an organ.
CAS-48179-M5G5	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Human error led to loss of tissue blocks.
CAS-48225-C4J7	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Miscommunication led to release of a body against family wishes
CAS-48387-P8V8	Viewing of the wrong body	Ineffective communication led to viewing of the wrong body
CAS-48465-G7X2	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-48588-Y8V6	Release of the wrong body	Human error led to the release of the wrong body.
CAS-48602-M1B1	Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family	Inadvertent disposal of a fetus less than 24 weeks gestation
CAS-48608-T8H8	Release of the wrong body	Human error led to temporary release of the wrong body
CAS-48610-T0D8	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-48720-C8J3	Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	Post Mortem conducted was not in line with the Coroner's request.
CAS-48764-H8F1	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Release of a body led to a complaint by a family
CAS-48800-B6S3	Release of the wrong body	Human error led to the release of the wrong body.
CAS-48903-D9F7	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to a delayed cremation and therefore retention of fetal tissue.
CAS-48938-L5S3	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to loss of traceability of fetal remains

CAS-48940-X0B4	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Human error led to a delayed cremation and therefore retention of fetal tissue.
CAS-48992-C9F1	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-49171-W1M1	Serious security breach	Security breach resulting in theft of staff belongings
CAS-49244-S2L5	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 incorrect disposal of pregnancy remains
CAS-49250-Z8Y5	Serious security breach	Failure to follow procedure led unauthorised access to the mortuary.
CAS-49251-X2B5	Major equipment failure	Fridge failure led to transfer of bodies to a temporary fridge unit.
CAS-49737-Y8Y7	Accidental damage to a body	Human error led to accidental damage to a body.
CAS-49739-R2B9	Release of the wrong body	Human error led to the release of the wrong body.

Authority Report

Development – Quarter One 2019/20

Date	18 July 2019	**Paper Reference**	HTA (18/19)
Agenda Item	9	**Author**	Allan Marriott-Smith
Protective Marking	OFFICIAL	**Author Contact** allan.marriott-smith@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 change 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 16a/19 for detailed information)**		

Purpose of paper

1. To provide the Authority 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 4 July 2019.

Action required

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

Director's summary

5. The Executive has made good progress on a number new and ongoing development projects during quarter one.

6. Reprioritisation of the HTA Development Programme has progressed slightly slower than anticipated, although it is expected that this work will be completed during quarter two.

Project updates

Core 2019/20 projects

7. 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

8. Work is ongoing to implement the recommendations of the HA risk project in three key areas – third party agreements (TPAs), preparation process dossiers (PPDs) and inspections. Work to date has focused on the first two of these.

9. Procedures have been put in place for gathering up-to-date information about TPAs as part of the inspection planning process and for reconciling this with the information held by the HTA on CRM; training has been provided to RMs on the new process. A comprehensive review of public-facing information relating to TPAs has been conducted and the website and forms amended accordingly. Legal advice is currently being sought about the scope for restricting activities permitted under TPAs.

10. Benchmarking work aimed at improving the efficiency and consistency of the PPD authorisation process has been completed for all standard tissue types. A systematic review of PPD-related information held by the HTA for each establishment has also been completed and work is underway to address any gaps in tracked information. Separate audits have also been completed in relation to deemed authorised procedures (i.e. authorised preparation processes for which a PPD has not been submitted) and conditional authorisations. Work is underway to address the findings of these audits. Audit templates have been drafted and procedures are being developed to ensure PPD-related information in CRM is reviewed regularly and kept up-to-date.

11. The project is broadly on track to meet pre-agreed timelines for completion, although the associated KPI on the business plan is marked amber to reflect the fact that a small number of individual pieces of work are behind schedule due to resource constraints.

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

12. An oral update on the revisions to Code F (Donation of Solid Organs and Tissues for Transplantation) and the HTA's consultation on the Code will be provided in agenda item 14.

13. In quarter one, we sought early engagement through key stakeholder networks such as NHSBT's Taking Organ Donation to 2020 (TOTO2020) and liaised with NHSBT to ensure widespread awareness amongst professionals of the forthcoming consultation.

14. The HTA also provided updates on revisions to Code of Practice F and plans for consultation at the Transplantation Advisory Group and Stakeholder and Fees Group meetings in May, and the Wales Transplant Advisory Group (WTAG) meeting in June.

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

15. The Head of Business Technology is working with the Head of Development and the SMT to establish priorities for change prior to development of the appropriate business cases for the prioritised projects.

Office Move Project

16. The Head of Business Technology and Business Support Manager attended the second culture workshop meeting in Leeds on Monday 3 June. Further information on the aims of the workshop is provided in paragraph 41, HTA paper 19/19 (item 10).

17. At the all staff away morning on Monday 17 June, The Head of Business Technology and the Business Support Manager presented feedback on the meeting along with a series of photographs of the furnishings and décor.

Migration to Cloud Services

18. The Head of Business Technology has engaged the services of a consultancy to assist with identification of the HTA's current state of cloud readiness along with 'bronze', 'silver' and 'gold' options for a cloud migration.

19. Each option will improve on its predecessor in terms of the functionality to be delivered and will have indicative budgets attached to them.

Additional 2019/20 projects

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

PM Sector Development

21. The PM sector development work has progressed well and is coming to an end. The sector report 'Regulation of the Post-mortem Sector 2017-18: Shared Learning' was published on the HTA website and circulated via the May edition of the professional eNewsletter. It was also shared with members of HWG at their June meeting.

22. The report is aimed at all staff working in the PM sector, and those under their direction in the conduct of licensed activities, including Pathologists, Anatomical Pathology Technologists and those undertaking licensed activities in Maternity and A&E departments. The sector information and the learning gained from the investigation of HTARIs will provide a useful resource to help mitigate the risk of incidents occurring.

23. The updated guidance for the PM sector standards is in the final stages of review and will be published in the near future.

IA Sustainability Work

24. The Transplant Manager has now scoped the delivery of the project for the remaining part of the 2019/20 business year.

25. A paper detailing the work packages was discussed at the Transplantation Advisory Group on 8 May 2019. In particular, the group provided helpful comments on a draft letter which will address the wider governance that supports the role at hospital level, and proposed online training for IAs.

Fees Project

26. The fees project has now been fully scoped out with a series of working groups planned to undertake six separate work packages. Groups will meet throughout July to tackle each work package with a summary and a recommendation of which, if any, changes could be implemented in time for the 2020/21 fees announcement.

27. Initial recommendations made by the Licensing Fees Working Group will be presented during the Strategy Away Day in October 2019. The Fees proposals will then be reviewed by the Stakeholder and Fees Group during its October meeting with final proposals presented to the Authority at its November meeting.

HTA Annual Conference

28. This year, the HTA conference will be held on Wednesday 6 November 2019 at Mary Ward House in London. The conference will be a full day event aimed at a professional audience.

29. This year's programme is currently being finalised, and some of the plans include:

    - A joint establishment / HTA presentation based around preparing for HTA inspection, or recent experience of inspection.
    - Two keynote speakers who are non-sector, wider stakeholders, not directly involved in HTA regulation, however will provide an interesting take on issues that affect us and our licensed establishments.
    - An extended table discussion / workshop session that will cover various data and compliance related issues.

30. The planning and preparation is underway for the conference; during quarter two we will open registration for the event, launching initially via the professional newsletter (establishments have already had a "save the date" message).

31. We will have larger capacity this year, with approximately 30% more delegates.

32. The communications team will be meeting regularly with staff across the organisation to ensure there is input from each sector team.

33. We will also seek feedback and participation from Authority Members.

Annual Compliance Updates

34. To support our system of continuous licensing, every licensed non-HA establishment is required to provide us with a biennial update of licensing information and to complete a concise, sector-specific questionnaire, focussed on risk and compliance with our standards. The compliance updates supplement our inspections programme and so contribute to our regulatory oversight of the HTAct and ODT sectors.

35. While the core administrative checks remain the same for each round of compliance updates, the sector-specific questionnaires are adapted to keep pace with key risks and trends in activities or non-compliances. The questions, which are informed by trends, findings or concerns we have noted, for example from inspections, are used to:

    - assess each establishment's compliance with our licensing standards and assessment criteria;
    - gather updated, establishment-specific information on the level and range of licensable activities;
    - gather intelligence to form a snapshot of activities across sectors;
    - identify higher-risk establishments, primarily to prioritise inspections within sectors.

36. As we have an embedded framework using the portal we are following the same process and templates as last time, with refreshed questions. We remain on target to deliver within projected timelines.

EU Exit

37. At the beginning of quarter one, in light of the Article 50 extension, the HTA stepped down planning activities for EU Exit.

38. The legal default in UK and EU law remains that, until a deal is agreed and ratified, there is a risk of a no deal exit at the end of the extension period on 31st October 2019.

39. All of the HTA's no deal measures therefore remain in place to be enacted as needed. We have continued to contribute to DHSC's planning activities, participate in various ALB EU Exit teleconferences and meetings, respond to stakeholder enquiries and disseminate information as needed.

Developing learning resources for licensed establishments

40. Members will recall that the Licensed Establishment Engagement Programme (LEEP) team were tasked with examining options to develop and deliver a potential DI training

package. Part of this work was to examine the feasibility and financial implications of providing HTA training for those working at licensed establishments.

41. Currently, the HTA has a number of key projects underway with considerable resource demands across the organisation. Our limited resources must be deployed strategically, and priority be given to those pieces of work considered the most critical to carrying out our function, in addition to our regular inspection and licensing commitments.

42. Our current plan is therefore to develop new materials as far as is practical, and to continue to update and improve our existing resources. We will ensure our information is as clear and accessible as possible, whilst making the most of opportunities to engage with our professional stakeholders. These include:

    - Improving the information available on the website for licensed establishment contacts;
    - Taking advantage of more face-to-face opportunities. We have increased the capacity at the 2019 annual conference in response to the large waiting lists we see each year;
    - In addition to our annual conference, we are looking at collaborating with sector stakeholders at their key events, such as AAPT, RCPath, HRA, IAS and BTS. LEEP are currently looking at other key events that we could participate;
    - Improving the information that is already available on our licensing requirements.

43. There is a core development project on the Business Plan for 2019/20 focusing on our licensing requirements, to ensure that existing and future HTA-licensed establishments are aware of, understand, and can access advice and guidance on which licence(s) they requires, and what to do.

44. As part of this work, LEEP have started to work on:

    - updated HTA licensing flowcharts, that we intend to develop into an accessible, interactive digital tool that will make our licensing requirements clear;
    - developing a guidance document for those working in key roles at licensed establishments explaining the roles and responsibilities under the HT Act, Q&S Regulations and ODT Regulations for the DI, Licence Holder, Person/s Designated and Named Contacts (ODT).
    - developing a series of webinars to supplement our online resources, such as the online tests.

Development KPI narrative

Performance against 2019/20 KPIs

45. KPI 1 (HA Risk) and KP1 5 (Updates to Code F) are marked as amber for quarter one to reflect the resource constraints limiting progress with the HA risk project (KPI 1) and the significant delay to the launch of the Code F consultation (KPI 5).

46. All other Development KPIs for quarter one are within target or tolerance and marked as green.

Projects scheduled to start in the next six months

Project	Brief description	Start date
Website development	Improvements to the structure and design of the HTA's website in order to better meet the needs of users, and meet statutory accessibility requirements	Subject to approval
Data and risk	Improved design of the HTA's risk-based approach to regulation through the better use of data, which will require scoping prior to formal approval.	Subject to approval

Authority Report

Deployment – Quarter One 2019/20

Date	18 July 2019	**Paper Reference**	HTA (19/19)
Agenda Item	10	**Authors**	Richard Sydee Allan Marriott-Smith
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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)	Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly) Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly) 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) 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); 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 16a/19 for detailed information)**

Purpose of paper

1. To provide the Authority 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 11 July 2019.

Action required

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

Directors' summary

5. Good progress has been made on a number of people-related initiatives during quarter one. The transition to a new Head of HR has proceeded smoothly as has the migration to the CascadeGo system.

6. Our cadre of RM's is increasingly well-established. A number of vacancies exist which will pose risk to the achievement of our change plans if not successfully appointed. In particular, the Director-level vacancy presents difficulties of stretch within the senior management team in the short term and is likely to slow the progress in planning the HTA Development Programme.

7. At the end of quarter 1 the HTA is broadly in line with its budgeted position, with a small net deficit of £1k between planned income and expenditure. A review of planned expenditure for the remainder of the year has identified a small surplus, we will continue to monitor this position and review again at the end of quarter 2, when our second and final round of invoicing is complete.

People

Stress Survey and Audit

8. A stress survey and audit were carried out by Capita in January to assess the level of work-related stress across the organisation and the stress triggers that are impacting our employees. The themes surveyed were: Workload, Control, Support, Relationships, Induction and Change. Of the approximately 77% who responded to the survey, 52% reported they often or always felt stressed at work, with 29% believing this negatively impacts their work and 32% saying this also had a negative impact on home or social life.

9. Relationships and Support were generally considered positive by respondents. Workload, and specifically time pressure, appears to be the most significant trigger contributing to stress.

10. In response to the results and recommendations a number of initiatives will be introduced throughout 2019. These include: a review of our HR policies, the development of a corporate risk assessments to gauge individual stress triggers, a targeted training programme to provide the language and tools to enable employees to both highlight and reduce work related stress and a wellness programme to support employees with both mental and physical health. The HTA will train approximately 15 employees as Mental Health First Aiders and the SMT has led a number of workshops across the organisation to better understand the workload related pressures in each business area.

11. Our group training in 2019/20 will focus on tools and techniques to assist in the management of pressure and stress. The following training sessions have been confirmed with external providers: Wellbeing workshops (eight sessions); Identifying stress and stressors; Resilience; Mindfulness and work/life balance and Coping with change.

GDPR compliance

12. The new HR system, CascadeGo, has been launched on a phased roll out to replace the existing system and to ensure that the HTA can more readily comply with data protection requirements with respect to staff records. All active employees personnel files have been migrated to the new system and employees have been trained on how to review their personal information and request and record annual leave.

13. All hard copy personnel files (both active and previous employees) have been reviewed and assessed against the retention schedule ensuring our compliance with GDPR

requirements. The hard copy files will be migrated to CascadeGo before the office move in 2021.

Pay remit and award 2019/20

14. The pay remit for 2019 / 2020 has now been published. The base remit has remained at 1%, as in previous years, but with an option for organisations to award a further 1% based on the affordability for that organisation. There will not be any Treasury funding to support this discretionary additional increase. The SMT will assess the options available for the HTA and the Remuneration Committee will take a decision on which option to pursue at its meeting in July.

PDPs, training and induction

15. The target for completing the PDP process is the end of June and a programme to support Individual, Career Investment Scheme and Group training will be put in place by the end of quarter two.

16. Based on the training needs analysis that was completed in January for all staff, SMT has approved the following group training courses: Effective Assertiveness and Vulnerable People training. In addition, staff will be trained how to complete work-related Risk Assessments. Further training will be considered as we move through the business year dependant on the available budget.

17. The RM induction programme has been launched, we will continue to monitor the effectiveness of the programme and make adjustments as necessary. All induction documentation will be uploaded into CascadeGo to facilitate completion tracking and ensure a consistent and enhanced new starter experience, leading to improved knowledge sharing and early engagement.

Recruitment and retention

18. The following vacancies have been filled during quarter one. The Head of Regulation (PM&PD), has now been permanently filled on promotion. The new Head of HR has joined effective from 4 June. The new Business Support Manager joined effective from 1 April. The Head Planning and Performance has been appointed and will join the HTA on 27 August.

19. Also in quarter one, we have appointed a Regulation Manager to lead on RM training and induction. This appointment is on secondment with a remit to develop this role effective from 1 May. We have decided not to pursue the second training manager role at present.

20. We currently have six vacancies entering quarter two. The Director of Regulatory Development post and three roles which aim to build our change capability: a Project Manager; a Data Analyst; and a Business Analyst. In addition we have two full-time Administrative Assistant vacancies.

HR Policies

21. We have reviewed and relaunched the Flexible Working policy and have introduced a new Working from Home policy. We have also approved a Stress Management and Wellbeing policy. These were launched at the all staff away morning on 17 June.

22. Revisions have also been agreed to the Bullying and Harassment policy, the Disciplinary policy and the Grievance policy.

Finance

Financial position for Q1 2019/20

Table one: summary position

HUMAN TISSUE AUTHORITY
Summary Management accounts for the period
For the Three Months Ending 30 June 2019

	Year-to-date				
	Actual	**Budget**	Var	Var	**Forecast**
	£'000s	**£'000s**	£'000s	%	**£'000s**
INCOME					
Government Grant in Aid	225,425	240,675	(15,250)	(6.34%)	870,700
Licence Fee income	1,421,030	1,455,755	(34,725)	(2.39%)	3,709,580
Devolved Governments	133,572	136,011	(2,439)	(1.79%)	133,572
Rental income	77,072	92,484	(15,412)	(16.66%)	308,289
Other income	11,807	11,250	557	4.95%	45,787
TOTAL INCOME	**1,868,906**	**1,936,175**	**(67,269)**	**(3.47%)**	**5,067,927**
OPERATING COSTS					
Staff costs (salaries etc)	750,838	809,517	(58,679)	(7.25%)	2,976,345
Other staff (exc inspecton)	25,204	30,700	(5,496)	(17.90%)	130,254
Authority costs	41,601	44,652	(3,051)	(6.83%)	188,749
Inspection costs	17,347	27,500	(10,153)	(36.92%)	99,847
Leaflet costs	2,718	2,250	468	20.81%	8,718
Communication costs	1,561	10,325	(8,764)	(84.88%)	26,166
IT and Telecom costs	92,110	85,270	6,840	8.02%	347,940
Office and Administration	21,632	19,344	2,288	11.83%	73,763
Other costs	14,100	14,875	(775)	(5.21%)	61,850
Legal and Professional costs	12,691	10,000	2,691	26.91%	70,941
Accommodation	207,869	203,375	4,494	2.21%	834,494
Non-cash	53,658	49,750	3,908	7.86%	202,908
Contingency		0		0.00%	15,500
Total operating costs	**1,241,328**	**1,307,558**	**(66,230)**	**(5.07%)**	**5,037,475**
Net Income/(expenditure)	**627,578**	**628,617**	**(1,039)**	**(0.17%)**	**30,452**

23. Table one (above) provides a summary position at the end of quarter one of the 2019/20 financial year, a year to date net deficit against budget of **£1k**.

Income

24. Table two shows the breakdown of income to date. Variation to budget within our grant in aid is a result of changes to the mechanism for funding and paying the increased NHSPS employers pension contributions (**£15k**). This does not impact on the net cost to the HTA.

Table two: income summary

Human Tissue Authority
Member Income Summary
For the Three Months Ending 30 June 2019

	Year to Date			
	Actuals	**Budget**	**Variance**	
	£	**£**	**£**	**%**
Grant In Aid				
GIA	176,000	168,250	7,750	4.61%
Non Cash cover	49,425	72,425	(23,000)	-31.76%
Sub-Total	**225,425**	**240,675**	**(15,250)**	**-6.34%**
Licence Fees				
Application Fees	20,460	0	20,460	0.00%
Anatomy	0	0	0	0.00%
Post Mortem	0	0	0	0.00%
Public Display	0	0	0	0.00%
Research	(2,305)	0	(2,305)	0.00%
Human application	1,402,875	1,455,755	(52,880)	-3.63%
ODT		0	0	0.00%
Sub-Total	**1,421,030**	**1,455,755**	**(34,725)**	**-2.39%**
Other				
Other income (Rent)	77,072	92,484	(15,412)	-16.66%
Other income (Secondees)	11,807	11,250	557	4.95%
Devolved Assemblies	133,572	136,011	(2,439)	-1.79%
Sub-Total	**222,451**	**239,745**	**(17,294)**	**-7.21%**
Total Income	**1,868,906**	**1,936,175**	**(67,269)**	**-5.27%**

25. Within the Human Application sector we have a short-fall of **£53k,** where licences have been revoked (2), suspended (2), or where activities have changed after the budget

was set. The shortfall in our rental income is due to VAT that has not been accrued from our sub-tenants whilst an outstanding issue remains unresolved.

Expenditure (by exception)

26. **Staff costs (salaries) and Authority costs** - year to date we are under budget by **£59k** (7.3%) and this is mainly due to vacancies being carried at Head and Manager level since the start of the year. We have used temporary staff to cover the junior positions which has not significantly impacted our overall costs. We currently have two Authority Member vacancies which is reflected in the year to date variance of **£3k.**

27. **Inspection costs** – are below budget by **£10k**. This reduction may be due to the rescheduling of inspections to later in the year. It may also be a result of the alternative travel arrangements being made as a result of the amended Travel and Subsistence policy. A review of its impact will be undertaken.

28. **Communication costs** - are underspent against budget by **£9k.** The underspends are mainly within our media monitoring service where the contract costs will now be lower than budgeted.

29. **IT and Telecom costs** – are overspent by **£7k.** This overspend relates to spends within consumables where items of expenditure that are outside our capitalisation policy (**£4k)** have been expensed. In addition a planned overspend in IT consultancy related to the upgrade of CRM (**£6k**)**.** Offsetting these overspends are underspends within IT support, photocopier and telephone costs.

Forecast outturn

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

31. Currently we are forecasting a small surplus of **£30k**. This takes into account all known plans and activities. However, we will continue to review our position at the end of each quarter to ensure we report the most up to date position possible.

Other key performance indicators

Debtors

32. Our outstanding debtors as at 30 June 2019 is **£640k** compared with **£334k** in the same period last year. The outstanding amount is represented by **69** accounts of which **27**

(£116k) relate to the 2018/19 business year.[1] We are contacting these establishments initially by telephone with a follow-up letter that will come from either the Director of Regulatory Delivery or the Chief Executive. There is a risk that a small number may not be collected before the September billing run, however we will continue to follow these up before requesting any regulatory action available.

33. During the three months to 30 June 2019, we issued invoices to the Human Application sector totalling **£1,421k.** Of this, **£544k** is outstanding. These, in addition to those from the end of the 2018/19 business year, are now being actively pursued.

34. Below is a breakdown by sector of the outstanding debts as at 30 June 2019.

Table Three: Debtors by sector

Sector	Number of accounts	Value of debt £	%ge
NHS	£371,290	44	63.8%
Government Bodies	(£1,515)	2	2.9%
Non Government Bodies	£271,196	23	33.3%
Total	£640,971	**69**	**100.0%**

35. A majority of the NHS accounts outstanding have now provided purchase orders which usually means that payment will be forthcoming, albeit around 30-60 days after they were issued.

Financial risks

36. Financial risks are monitored on an ongoing basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – is currently rag status yellow as we have a challenging budget due a small decline in licence fee income. As of quarter one, we are forecasting a small underspend.

[1] At the time of writing this commentary, the 2018/19 debtor balance is £97k.

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.

Digital, data and technology and working environment

Business technology

37. Since the last report we have reduced the number of high impact vulnerabilities identified by penetration testing to zero and medium impact vulnerabilities have been reduced to 49.

38. We have compiled a comprehensive list of outstanding CRM change requests which is being reviewed by our developers.

39. In this quarter we have given focus to improving IT service delivery and IT operations management. We have developed plans to make improvements in the short to medium term and working towards a longer term strategy, giving thought to the future shape of IT support after the office move.

Information and Data

40. We have drafted a records management policy and a detailed records retention schedule and we are undertaking a gap analysis prior to implementation of the policy to better understand where to direct our resources.

Working environment

41. We have attended a further culture workshop hosted by the DHSC at Quarry House in Leeds. The aims of the workshop were to:

    a. Identify how we use our workplace and understand how others use theirs
    b. Agree principles of how we work together to effectively use the workplace at Stratford and use these principles to resolve any sticking points in how we share the space
    c. To see how the department are designing their own workspaces for smarter working

42. We have presented the outcomes of this workshop to all staff.

Deployment KPI narrative

Performance against 2019/20 KPIs

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

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

Authority paper

Date	18 July 2019	**Paper reference**	HTA (20/19)
Agenda item	11	**Author**	Maria Paulina- Socarras
Protective Marking	OFFICIAL		

Stakeholder and Fees Group Update

Purpose of paper

1. To update the Authority on the Stakeholder and Fees Group (SFG) meeting which took place on 29 May 2019.

Decision-Making to date

2. This report was approved by the CEO on 4 July 2019.

Background

3. The HTA's Stakeholder Group was set up in November 2013 following a recommendation from Justin McCracken's review of the HTA and HFEA.

4. The Group contains members from organisations we license, umbrella bodies such as the British Medical Association, members of the public, and patient groups.

5. The meeting in May was the eleventh Stakeholder Group meeting.

HTA updates

6. During the meeting, updates were provided on the licensing and fees project, digital transformation project, developing learning resources for licensed establishments, EU exit, the HA risk project, the HRA/HTA public dialogue work and deemed consent in England.

7. The rolling horizon scanning agenda item flagged policy updates from the HTA on organ perfusion devices and recent press coverage of taphonomy. SFG Members likewise shared policy updates on consent and the retention of blocks and slides and unethical organ harvesting in China.

Substantive matters raised

Deemed consent for organ donation in England

8. The Group was informed that the HTA is launching a consultation on revisions to Code of Practice F in light of the introduction of deemed consent for organ and tissue donation in England.

9. Members were presented with an overview of the main changes to the Code focussing on deceased organ and tissue donation and how deemed consent will affect clinical practice.

10. The Group expressed some concerns with the lack of clarity on what the deemed consent system will mean in practice. In particular, representatives from the Anatomy sector felt there is some confusion from the public with regards to possible links to body donation and taphonomy.

11. HTA staff present at the meeting assured the Group that we will be explicit in our public guidance (particularly in our Public Guide to Code F) on what the changes will mean for individual consent.

Fees and licensing project

12. SFG Members were provided with an update on the HTA's Fees and Licensing Project. The Group was informed that the project has been commissioned to explore areas where the licensing and fees structure may no longer be representative of the regulatory work undertaken by the HTA.

13. Members were advised that the project group will consider aspects of both the current licensing and fees structures, with the aim of exploring potential changes that will realign both with the regulatory work undertaken by the HTA across sectors and in relation to licensable activities.

14. Concerns were raised by establishments in the human application sector concerning how the proposed fees levels would be burdensome to those funded in the same way as the HTA. Suggestions were made by Members to look at how other organisations charge licence fees, as well as ensuring that we strike a balance between on our duty to provide advice and guidance and charging fees.

15. We assured members that the Finance Team are looking at a broad data set to inform their proposals. We also reassured the Group that the HTA are committed to ongoing SFG engagement on this project and its outcomes.

Future meetings

16. Members continue to be supportive of the Group and attendance has improved. It was proposed that the HTA should improve telephony and remote access to meetings.

17. The Group requested an update on the licensing and fees project, deemed consent, EU exit and an update on changes to the EUTCD at the October 2019 meeting.

Authority paper

Date	18 July 2019	**Paper reference**	HTA (21/19)
Agenda item	12	**Author**	Richard Sydee
Protective Marking	OFFICIAL		

Audit and Risk Assurance Committee Update

Purpose of paper

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

Decision-making to date

2. This report was approved by the CEO on 4 July 2019.

Action required

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

Background

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

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

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

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

Introduction

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

7. Membership of the ARAC through the year has been:

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

8. ARAC met three times in 2018/19. The Chief Executive, the Director of Resources, the Head of Finance and Governance, the HTA's external and internal auditor attended all meetings. Other directors and staff attended to discuss particular risk areas that ARAC wished to explore, or other topics depending on the ARAC's business. Colleagues from the Department of Health and Social Care also attend.

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

Review of Committee effectiveness

10. The Committee reviewed its effectiveness in the period March 2018 to March 2019. This consisted of members responding to a series of questions relevant to ARAC at this time. The questions were:

    a. What does ARAC do for the Authority?
    b. Does the annual cycle of business cover all that we should?
    c. Do ARAC papers cover what is needed? If not, what would be better?
    d. Do we have sufficient expertise on the committee and in internal/external audit attendees properly to scrutinise as we should?

e. Do we have sufficient time in meetings?
f. Are the training sessions valuable? If you feel you need more training, what would that cover?
g. Do you feel able to raise everything you would like to discuss?
h. Is there anything we could do better?

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

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

Risk Management

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

14. During the 2018/19 business year, ARAC identified risk areas to explore in greater detail and relevant staff attended meetings to provide more information and assurance on:

    a. HTA staff induction;
    b. Cyber security; and
    c. Preparedness for the HTA transformation programme.

15. The Committee reviewed the updated risk register at its June 2019 meeting.

Information and data security

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

17. During this period the ARAC has received regular reports on the progress GDPR implementation, response to IT and cyber incidents during the period as well as overall data and cyber security.

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

19. Throughout the year one potential data loss was identified, due to the use of an incorrect email address and this was dealt with in accordance with our policies and did not require formal notification to the Information Commissioners Office. Overall the SIRO considered that information risk was managed adequately. The Committee received a formal report from the SIRO at its last meeting.

Internal audit

20. During this period the Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress. In total 5 audits were undertaken across stakeholder engagement, GDPR implementation, records management, key regulatory processes and cyber security.

21. Internal Audit gave “moderate” assurance that the HTA had adequate and effective systems of control, governance and risk management in place for the reporting year 2018/19.

External audit

22. NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2018/19 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

Assurance processes

23. During 2018/19, the Chief Executive met with HTA Directors at least monthly (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to share information, review progress against business plans, review strategic risk, and make necessary decisions.

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

Governance statement

25. The Governance Statement is a key part of the Annual Report and Accounts. It is signed by the Accounting Officer and explains how governance responsibilities have been discharged. The Committee considers that there is sufficient evidence of

effective governance processes to support the signing of the Governance Statement. There are no material issues to be brought to the attention of the Accounting Officer or Authority.

Summary

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

Authority paper

Date	18 July 2019	**Paper reference**	HTA (22/19)
Agenda item	15	**Author**	Nicolette Harrison
Protective Marking	OFFICIAL		

The future of the Delivery Report

Purpose of paper

1. To prompt discussion among Authority Members about how the Delivery Report might be improved.

Decision-making to date

2. This paper was approved by the CEO on 4 July 2019.

Action required

3. Discussion at the Authority Meeting to help steer the Executive in re-designing the style and content of the Delivery Report.

Background

4. The Authority briefly discussed the style and format of the Delivery Report at its meeting in May 2019, resulting in an action for the Director of Regulatory Delivery (Nicolette Harrison) to bring a discussion paper to the next meeting.

5. Authority Members have suggested that more explicit linkage of the data and narrative sections would improve the Delivery Report and avoid many of the questions raised at the meeting as the information would become more self-explanatory.

6. Authority Members also felt that they would have more assurance on the Executive's management of regulatory delivery and risk by providing a more cohesive narrative

that more obviously showed insight gained and actions taken to manage identified regulatory risks.

7. Re-shaping the Delivery Report in this way could therefore improve the assurance the Authority gains about how the HTA is using this insight to fulfil its strategic objectives across the full range of operational activity, including communication activity.

8. The Authority may therefore be more concerned with being given information that allows it to understand the themes and trends and how the HTA is using these to inform its management of regulatory risk.

9. The HTA is also currently developing a ‘core data set’ of regulatory data and reviewing its publication scheme. This could result in the HTA publishing more information and data directly onto our website rather than through the Delivery Report. For example, publishing information on incidents quarterly, obviating the need for that information to be included in the Delivery Report.

10. A recent Regulation Directorate workshop also considered the format of the Delivery Report. This raised similar points to those made by Authority Members, for example, a preference for presenting data schematically, rather than in tables, and to publishing incident data on the website, with the Delivery Report having a narrative about the HTA’s views and action on any trends. The Histopathology Working Group has recently been given data and information using this approach, which builds on the work done last year to create the Safety KPI report and has proved to be helpful.

11. The communications team, which participated in the Regulation Directorate workshop on the Delivery Report and contribute a substantial amount of material to it on our communications activity, similarly proposed modifying the digital communications section to include more relevant data, presented schematically, on social media and website performance and use, to make these analyses more visual and easier to interpret.

12. As with the narrative for the more formal aspects of regulatory delivery, the Delivery Report could include a succinct and coherent narrative on the focus and progress of our communication activity, as part of the soft regulatory toolset we use to raise awareness of our role and requirements with those we regulate and the public.

13. Colleagues at the workshop also commented on the process by which the Delivery Report is produced, which can be very labour-intensive partly because of the volume of content and partly because of the constraints of the format. They suggested that streamlining it to focus on providing assurance to the Authority about how regulatory delivery was being used to take forward our strategic objectives would help it become less burdensome to produce and read.

Authority paper

Date	18 July 2019	**Paper reference**	HTA (23/19)
Agenda item	16	**Author**	Richard Sydee
Protective Marking	OFFICIAL		

HTA office relocation business case

Purpose of paper

1. To provide an update to the Authority on plans for the future office accommodation of the HTA.

Decision-making to date

2. This paper was approved by the CEO on 4 July 2019.

Action required

3. The Authority are asked to:

    a. Note the progress to date;
    b. Approve the intent to proceed with the move to Stratford and, subject to affordability, formal contractual commitment to the move.

Background

4. The HTA's lease on its current office accommodation, 151 Buckingham Palace Road, expires on 31 March 2021. The Department of Health and Social Care (DHSC) initiated a programme in mid-2018 to move majority of its Central London-based ALB estate to the outskirts of Greater London in line with the wider Hubs strategy for the Government's London estate.

5. Since the establishment of this programme, the HTA has expressed a preference to be located in one of these London Hubs, with the proposed Stratford site being the preference for the organisation.

6. The programme has created a specific project for the Stratford hub and this has progressed to the point where proposed tenants will soon be required to contractually commit to lease space within the Hub.

Location and facilities

7. The location is 2 Redmond Place, a new build office block in the expanding International Quarter development, which borders the Olympic Park. The HTA will be located on the second floor of the building, and will share the space with four other DHSC Arm's Length Bodies: the Human Fertilisation and Embryology Authority, Health Research Authority, Care Quality Commission and National Institute for Health and Care Excellence.

8. In total, the accommodation on the second floor will provide 360 work stations, 19 internal meeting rooms, a number of informal breakout and meeting spaces for collaborative working and other facilities including kitchen areas, multi-faith room and personal storage lockers for staff. In addition, there will be a shared conference facility that will provide a number of medium and large meeting rooms and a shared reception area.

Decision and construction timelines

9. The project team's initial focus has been to obtain the relevant support and clearance of the Government Property Agency, the Office for Government Property and the Cabinet Office. Once these clearances have been obtained (which is expected imminently) the project team anticipate that organisations will be expected to contractually commit to the move before September 2019.

10. In relation to design and construction timelines, at this time the five organisations have provisionally agreed the layout of the second floor. There is likely to be one further review of these plans before the project team moves to tender for the contractor to complete the internal layout of the floor. The building itself is expected to be structurally complete by late autumn with the floor plate being available for custom configuration from December 2019. The configuration work is planned to complete in September 2020, which should provide sufficient contingency and handover time for the first organisational moves in November 2020.

Finances

11. The cost of legal advice, surveyors and contractors to complete the fit out of the accommodation, including furniture, will be met by the DHSC. The Department will also fund project and programme support and the cost of physical relocation of organisations to the new accommodation.

12. Initial estimates in terms of accommodation costs suggest a saving of £250 per square metre on the current cost at Buckingham Palace Road.

13. Overall cost will be dependent on final space allocation, in particular the approach taken for shared areas, meeting space and the conference facilities. This will be finalised over coming weeks and ahead of signing contracts.

Staff

14. All HTA employees have been kept informed of the progress with the Stratford site with regular updates at all staff meetings. An office move focus group was established in March 2019 to directly involve staff across the organisation in the finalisation of designs and likely new ways of working in the new accommodation. This has included staff visiting new DHSC office accommodation in Quarry House, Leeds which is likely to be similar in terms of occupancy and facilities on offer.

15. We have initiated a formal communications plan, with updates posted on the HTA newsletters as we progress against the planned project milestones.

16. The response to the office layout itself has been positive, the new facilities provide a significant improvement on the existing accommodation. Inevitably the location presents commuting issues for some employees and as we move forward with our internal project our initial focus will be on considering how we can mitigate the impact of the move for staff - including review of existing home and flexible working policies as well as the provision of excess fares where appropriate.

17. Excess fares are likely to be considered in conjunction with other bodies to ensure parity for all staff relocating to Stratford.

Risks

18. We have drafted a new risk for the HTA's strategic risk register which establishes a number of areas where the office relocation could impact on the delivery of our operational and strategic goals. These include, but are not limited to:

    - Move to Stratford leading to increased staff turnover;
    - Staff resource diverted to relocation activity impacts on operational delivery;
    - Post-move facilities not meeting all HTA requirements.

19. We will be conducting detailed surveys with our staff over the coming weeks to establish the individual impact the relocation poses and will be working over the summer and autumn to develop responses to these issues that will mitigate the impact on staff.

20. Our overall engagement with the project and partners, to date, provides some confidence that the project can proceed smoothly. We will be working with our partners to ensure all organisational needs are catered for and that appropriate project and logistical support is provided to the HTA to mitigate the impact on business as usual activities as we prepare for the move.

Authority paper

Date	18 July 2019	**Paper reference**	HTA (24/19)
Agenda item	17	**Author**	Nima Sharma / Jessica Porter
Protective Marking	OFFICIAL		

Out-of-hours consideration of emergency living donation cases

Purpose of paper

1. The purpose of this paper is to enable Authority Members to discuss the risks, benefits and concerns of the process for out-of-hours consideration of emergency living donation cases.

Decision-making to date

2. This paper was approved by the CEO on 4 July 2019.

Action required

3. Authority Members are asked to note and comment on the content of this paper.

Concerns and Issues

4. During the May Authority meeting, some Members raised concerns about taking part in the on-call rota for the out-of-hours consideration of emergency living donation cases. Members highlighted that involvement in the out-of-hours rota had not been highlighted to them during their appointment process.

5. The HTA Chair agreed that these issues could be discussed at the July Authority meeting.

Background

6. At present, there are 13 people on the rota; all 10 Authority Members and three members of staff within the Senior Management Team (SMT). Each person is allocated a two-week period where they are asked to provide out-of-hours cover; this cover period starts on a Monday at 5pm. On rare occasions where there is a gap in cover, the Head of Regulation for Organ Donation and Transplantation provides cover.

7. The Living Donation Team circulate HTA-SOP-113 Business Continuity and Out of Hours Assessment of Living Donor Transplant cases (Annex A) and HTA-TEM-006 Living Organ Donor Assessments- Emergency Out of Hours Assessment (Annex B) to the person on the rota at the start of each cover period. These documents provide information about the process that should be followed to consider and make a decision on such cases. The documents have been amended following feedback from those that have provided decisions on emergency living donation cases. The Living Donor Coordinators are also expected to follow the HTA's Guidance on Living Organ Donation Assessments, HTA-GD-022 (Annex C).

8. Authority Members and SMT are usually on the rota for a minimum of 14 calendar days per year, and a maximum of 28 calendar days per year. This means those on the rota are currently asked to provide out-of-hours support for one or two cover periods each year.

9. Since 2014, a total of 12 HTA approvals have been given out of hours. This is an average of two cases per calendar year over the last five years.

Discussion

10. Members are invited to discuss their views of the current process. The following points are to support this discussion:

    - Members are responsible for considering cases requiring a decision by panel. With this in mind, Members are well placed to provide decisions on living donation cases where there is an urgent clinical need for a recipient to receive a transplant, having more experience than the Senior Officers of the Authority in this regard.

    - The individuals with the greatest knowledge in this area are a small number of relatively junior staff. They do not currently provide this cover and placing this responsibility upon them has not been considered reasonable historically.

    - As the number of emergency out-of-hours cases considered by the HTA for approval has been relatively low over the last five years, the Executive recognises that it may be useful for refresher training on the processes to be followed during the consideration of such cases to be provided (see paragraph 11 below).

- Colleagues in our sponsor team at Department of Health and Social Care involved in advertising this role have been notified that future applicants should be informed about the out-of-hours rota.

Further work

11. The Living Donation Team will conduct annual refresher training once a year. This will be delivered during one of the regular panel teleconferences.

12. Occasionally, Living Donor Coordinators may notify the Living Donation Team that an emergency out of hour's case will need to take place. This enables the Living Donation Team to notify the member of staff on the rota to expect a phone call. As this has been helpful in the past, the Living Donation Team will remind all Living Donor Coordinators of this expectation, where it is possible, via the next Living Donation newsletter.

STANDARD OPERATING PROCEDURE

Version	16.3	**Date approved**	October 2017
Reference number	HTA-SOP-113	**Next review due**	October 2018
Author(s)	Rosie Bate	**Owner**	Transplant Manager
Reviewed by	Chitvan Amin	**Distribution**	Authority Members, SMT, LDAT
Approved by	Jessica Porter		

Business continuity and out of hours assessment process for living donor transplant cases

Abstract

1. This document outlines the emergency out-of-hours assessment process for living donor cases. It also documents the differences where the emergency out of hour's process is used in routine situations and in business continuity situations.

Purpose

2. To ensure emergency processes are followed to enable the on-call HTA representative (HTA Authority Member) to follow the steps to make a decision on an emergency living organ donation case.

Outcome

3. A decision is made on whether or not to approve an emergency living organ donation.

Scope

4. Annex A describes in detail the types of living organ donations for which emergency out of hour's approval can be granted by the HTA representative.

A. Details of emergency out of hours procedure

Event 1: How the HTA on-call representative is contacted for an emergency out-of-hours decision and the next steps.

Note: If the LDAT is informed in office hours of a possible emergency out of hour's case by a transplant unit, the on-call HTA Representative **must** be notified in advance.

HTA representative receives a call from the transplant unit about an urgent emergency case. The HTA emergency number is 0207 269 1991. These calls will be received out of office hours and during weekends.

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If the HTA representative does not answer then the transplant unit will leave a message for them.

The transplant unit will try to contact every 10 minutes until the HTA representative responds. If after an hour the transplant unit is unable to contact the HTA representative, they should contact one of the back-up contacts. The back-up contact is the Head of Regulation for Organ Donation sector or the Transplant Manager. Their contact numbers can be found in Annex B.

↓

HTA representative speaks with the Living Donor Coordinator to clarify

- there is a clinical need for emergency transplant
- case information
- whether the donor and the recipient have been interviewed by an IA
- telephone contact details of the IA
- telephone and email contact details of Living Donor coordinator responsible for the case

If the donor and the recipient have not been interviewed by an IA (either face-to-face or by phone) then the HTA representative should inform the transplant unit that this must take place before the HTA can assess the case. Where it is not possible to interview the recipient, the reasons for this must be clearly explained.

↓

HTA representative contacts the IA to get details of the IA interview and assesses the case using the emergency out-of-hours checklist.

Event 2: HTA representative assesses the case

Step 1 - **A checklist is provided, via email to the HTA representative to support this step.**

For all emergency assessments, the HTA representative must ask the IA the following questions to ascertain whether the requirements of the Human Tissue Act 2004 and associated Regulations have been met (based on the IA's interview with the donor and recipient):

At the outset you should establish:

- The name and DOB of the donor (confirm the **donor** is not a child under 18 or adult lacking capacity as these will not be emergencies. See Annex A)
- The name and DOB of the recipient
- The type of transplant (see Annex A)
- The type of organ to be transplanted (e.g. liver)
- A description of the relationship between the donor and recipient and any evidence that has been seen to support this.
- Confirm that the donor and recipient have been interviewed separately and together (this may not be possible if the recipient lacks capacity).
- Whether there were any difficulties communicating with the donor and/or recipient (e.g. language, hearing). If so, how were these overcome? (E.g. for language difficulties, an independent translator must be used.)

With regard to the donor interview you should seek:

- Confirmation that a registered medical practitioner has explained to the donor the nature of the medical procedure, the risks involved (including the risk of death). In Scotland, confirmation that the donor has considered any other wider implications is also required.
- The name of the person giving this information and their qualification to give it.
- An assessment of capacity of the donor to understand and accept of the nature of the procedure and risks involved.
- Confirm that the donor understands they are able to withdraw consent at any time.

For both donor and recipient you should seek:

- A summary of the discussion had with the donor and recipient in order to determine that there was no evidence of duress or coercion affecting the donor's decision to consent, or any evidence of an offer of a reward.

Step 2 Based on the evidence provided by the IA, the HTA representative must make a decision on whether or not to approve the donation. Should the HTA representative require legal advice for the case, the following law firms operate an emergency out of hours telephone service (between 5.30pm and 9.00am): Mills and Reeve: **01384 679 023** Hill Dickinson: **07715 376 624**
Step 3 Once the HTA representative has made a decision they must call the transplant unit to let them know. The HTA representative must also record in writing the outcome of their decision and why they were, or were not, satisfied that HTA requirements had been met. This decision should be emailed to the Living Donor Coordinator *(remain aware of security and disclosure of personal information / patient data on non-secure networks)* and transplants@hta.gov.uk . The HTA Representative should post or email (transplants@hta.gov.uk) the checklist to the LDAT who will upload the document to the notes section of the case once the IA has submitted the report via the portal (event 3, step 2 below). The LDAT will then confidentially dispose of the checklist.

Event 3: IA submits a retrospective report to the HTA via the portal

Step 1 IA submits report via the portal and the LDAT checks with the HTA representative who assessed the case that the reported information reflects the conversation had with the IA. A 'T' Number will only be generated once the IA submits the report via the portal.
Step 2 The LDAT uploads the HTA representative's checklist to the notes section of the IA report, records the decision on the online system, providing information in the notes section of the report and ticking the box to confirm that it was assessed during out-of-office hours and explaining the reasons for this (including that there was a proven clinical need).

B. Details of business continuity procedure

Event 1: The role owner (Head of Regulation for ODT) is notified in the event that remote servers (live or disaster recovery (DR) servers) are unavailable. In other business continuity situations the Living Donor Transplants, role owner should refer to the transplants role sheet as part of the Critical Incident Response Plan and Roles (HTA-BCP-03).

Step 1 The role owner will notify IT admin to forward the emergency out of hour's phone to the transplants role owner mobile for both office hours and out of hours.
Step 2 The role owner will notify the current HTA representative that the out of hour's phone is no longer forwarded to them as the HTA is now in business continuity mode without remote server access.

Step 3 NHSBT will be notified that all living donation cases will now follow the emergency out of hour's procedures.
Step 4 All transplant units (both for living organs and bone marrow/PBSC) will be notified that the HTA is reverting to emergency procedures where verbal agreement will be given and a retrospective report submitted. Transplant units will be advised that only emergency cases are to be referred to the HTA and all other cases will be postponed until further notice.
Step 5 The role owner will notify all Authority Members and relevant transplant units that all panel cases are on hold until further notice.

Related documents

- HTA-SOP-111 Assessment process for living donor transplant cases
- Emergency out-of-hours HTA assessments – Guidance for living donor coordinators
- Emergency out-of-hours: Checklist
- HTA-BCP-03 Critical Incident Response Plan and Roles

Review

5. The SOP should be reviewed after each use or annually otherwise.

Revision history

Date	Version	Comments
8 June 2007	V0.1	
5 August 2008	V0.2	
9 December 2009	V0.3	
August 2010	V0.4	
9 January 2013	V0.5	AMS reviewed and amended as part of the Governance Documentation Project.
28 March 2013	V 1.0	Approved by Director
4 September 2013	V 1.1	Law firm details added should advice be necessary
21 March 2014	V 1.2	Reviewed by Jess as part of annual governance review and approved by AMS.
31 December 2014	V 1.3	Reviewed by Katy to include business continuity emergency cases
26 January 2015	V 1.4	Reviewed by Jess now that business continuity processes have been incorporated
23 March 2015	V15.0	Additional review undertaken by Jess as part of annual governance review. Approved by Allan.
August 2016	V16.0	Reviewed by CA as NHSBT contact details are removed from Process. Approved by Head of Regulation.
November 2016	V16.1	Added living donor coordinator to be sent a written confirmation for the transplant approval by Chitvan. Approved by Jess.
May 2017	V16.2	Amended the process to make it clearer for the HTA representative, based on recommendations made by Authority members. Approved by JP.

September 2017	V16.3	Amended the process regarding what the HTA Representative does with their checklist once approval has been given to an emergency case. Critical Incident Response Plan and roles SOP hyperlink was added. Approved by JP.

Annex A

Emergency living organ donation cases

Living organ donation cases which **can** be assessed in an emergency are:

- Directed- adult to child kidney and liver donations
- Directed- adult to adult kidney and liver donations

Living organ donation cases which **cannot be** assessed in an emergency situation because the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 s.12 (1) require that a decision on these cases must be made by a panel of no fewer than three Members of the Authority:

- Non-directed altruistic donations
- Paired or pooled donations
- The potential donor is an adult who lacks capacity or the donor is a child under 18 years old (in addition to being approved by the Authority, court approval needs to be obtained before the case can be assessed).

As a matter of policy the following cases **will not be assessed** in an emergency out of hour's situation:

- Directed altruistic donations

Please refer to GD-022 Emergency Living Organ Donation Assessments - Guidance for Living Donor Coordinators for information on the steps Living Donor coordinators need to take.

Annex B

If the transplant unit is unable to contact the HTA representative, the Living Donor Coordinator should call the back-up contact. The back-up contact for HTA out of hour's emergency are

1. Head of Regulation for Organ Donation sector – Jessica Porter. Can be reached at 07731306402.
2. Transplant Manager – Chitvan Amin. Can be reached at 07894 437835.

LIVING ORGAN DONATION ASSESSMENTS

Version	16.1	**Date approved**	May 2017
Reference number	HTA-TEM-006	**Next review due**	May 2020
Author(s)	Jessica Porter	**Owner**	Transplant Manager
Reviewed by	Chitvan Amin	**Distribution**	Authority Members, SMT, LDAT
Approved by	Jessica Porter		

Emergency out-of-hours checklist

Use this document if you are the HTA representative on the 'Out of hour's' rota or the role owner for business continuity and have received a call from the transplant unit notifying you of an emergency case. You will need to check

- there is a clinical need for emergency transplant
- case information
- whether the donor and the recipient have been interviewed by an Independent Assessor (IA)
- telephone contact details of IA
- telephone and email contact details of Living Donor coordinator (LDC) responsible for the case

If an IA interview has already taken place, the Transplant Unit will give you the IA's contact details.

Please ensure when talking to the IA that you cover all the details in the check list provided below.

Interview question	Yes	No	Comments
Name and age of both donor and recipient. (Confirm the donor isn't a child under 18 or adult lacking capacity as these will not be emergency situations.)	☐	☐	Donor: Recipient:

Interview question	Yes	No	Comments
The type of transplant (e.g. adult to adult liver) and organ (e.g. liver).	☐	☐	Type of transplant: Organ:
Evidence of relationship that has been viewed (where possible) and evidence of identity.	☐	☐	Relationship: Identity:
Confirm that the donor and recipient have been interviewed separately and together (where possible).	☐	☐	If not, why not? E.g. recipient lacking capacity.
Any difficulties communicating with the donor and/or recipient (e.g. language, hearing). If so, how were these overcome? (E.g. for language difficulties, an independent translator must be used; for hearing, an independent person fluent in sign language should be used).	☐	☐	Donor: Recipient:
Confirm that the registered medical practitioner (or a person acting under the supervision of the registered medical practitioner) has provided the donor with the information he/she requires to understand the consequences of donation.	☐	☐	
Confirm that the registered medical practitioner is satisfied that the donor has capacity to consent to the donation.	☐	☐	
Confirm that the registered medical practitioner responsible for the donor is satisfied that the donor's health and medical history are suitable for the purposes of donation.	☐	☐	
Confirm that the registered medical practitioner has endeavored to obtain information from the donor that is relevant to transplantation.	☐	☐	

Interview question	Yes	No	Comments
Name and qualification of the medical practitioner responsible for the donor.	☐	☐	Name: Qualification:
Detail of the donor's understanding and acceptance of the nature of the procedure.	☐	☐	
Detail of the donor's understanding and acceptance of the risks involved (including the risk of death- 1:200 for adult to adult liver, 1:500 for adult to child liver). Donors do not have to be able to state the statistical data.	☐	☐	
SCOTLAND ONLY: Detail of the donor's understanding and acceptance of the other wider implications (for example the effect upon children / dependent relatives, convalescence period, work arrangements).	☐	☐	
Summary of the discussion had with the donor and recipient in order to determine that there was no evidence of duress or coercion affecting the decision to give consent.	☐	☐	
Summary of the discussion had with the donor and recipient in order to determine that there was no evidence of offer of reward affecting the decision to give consent.	☐	☐	
Confirmation that the donor understands they are able to withdraw consent at any time	☐	☐	

Interview question	Yes	No	Comments
Confirm the donor's decision about what they wish to happen to their organ / part organ in the event it cannot be transplanted into the intended recipient.	☐	☐	
Confirm that the IA has received the declaration on reward for the donor / person consenting on behalf of donor	☐	☐	
Any other comments:			

Next steps:

a) Based on the evidence provided by the IA, the HTA representative must make a decision on whether or not to approve the case.
b) Once the HTA representative has made a decision they must call the transplant unit to let them have a verbal decision. No 'T' number will be generated with this approval. A 'T' number will only be generated when the IA submits their report retrospectively through the HTA portal.
c) The HTA representative must also record in writing the outcome of their decision and why there were, or were not, satisfied that the HTA requirements had been met. This needs to be emailed to the LDC and the Living Donation Assessment Team (LDAT) at transplants@hta.gov.uk
d) The IA submits the report via portal and the LDAT checks with the HTA representative who assessed the case that the reported information reflects the conversation had with the IA.
e) The LDAT records the decision on the online system, noting in comments box that the report was assessed out-of-office hours and explaining the reasons for this (including that there was a proven clinical need).

August 2016	Reviewed by Chitvan	Approved by Jess 19.8.16
May 2017	Updated to include recommendations made by Authority Members	Approved by Jess

Next review date: May 2020

EMERGENCY LIVING ORGAN DONATION ASSESSMENTS

Version	16.1	**Date approved**	May 2017
Reference number	HTA-GD-022	**Next review due**	May 2020
		Owner	Transplant Manager
Reviewed by	Chitvan Amin	**Distribution**	Authority Members, SMT, LDAT
Approved by	Jessica Porter		

Emergency out-of-hours HTA assessments – Guidance for living donor coordinators

1. Please make sure that you have the contact telephone number(s) for the Independent Assessor (IA) who is carrying out the Independent Assessment for the emergency case. The HTA representative will need to be able to contact the IA to discuss the case.

2. Please also ensure that the HTA representative has your contact details.

3. If an emergency living organ donation case arises outside of HTA office hours (Monday to Friday, 9 am – 5 pm) and you need an emergency decision from the HTA, please follow the procedure below:

4. Contact the on call HTA representative by calling **020 7269 1991**. If at first there is no answer please try again for one hour.

5. If the transplant unit is unable to contact the on call HTA representative after one hour, the Living Donor Coordinator should call the reserve contact:

    1. Head of Regulation for Organ Donation & Transplantation sector – Jessica Porter: 07731306402 or;
    2. Transplant Manager – Chitvan Amin: 07894437835

6. The HTA representative will ask for confirmation that there is a clinical need for an emergency decision to be made.

7. The HTA representative will also ask for confirmation that an IA has interviewed the donor and recipient. If the donor and/or recipient have not been interviewed by an IA, either face-to-face or on the phone, then this must be arranged as soon as possible.

8. The HTA will not be able to assess the case or provide a decision until the interviews have taken place.

9. Where it is not possible to interview the recipient, please explain clearly the reasons for this to the HTA representative.

10. The HTA representative will then request the IAs name and contact number from you and the HTA representative will contact the IA to discuss the case with them.

11. As soon as the HTA representative has made a decision they will contact you to inform you of what the decision is and confirm this in writing via email.

Please note: **a 'T' number <u>will not</u> be issued when a verbal approval is provided. Instead, the HTA representative has to confirm in writing to the LDC that approval has been given.**

12. The IA is required to submit a retrospective report on the case as soon as possible, but in the first instance a verbal approval and an email approval will be given by the HTA representative so that no delays are caused. This is sufficient for the transplant to proceed. A 'T' number will be generated once the IA has submitted a retrospective report.

Authority paper

Date	18 July 2019	**Paper reference**	HTA (25/19)
Agenda item	18	**Author**	Richard Sydee
Protective Marking	OFFICIAL		

Licensing Fees Review

Purpose of paper

1. To provide the Authority with an overview of the proposed review of licensing fees.

Decision-making to date

2. This paper was approved by the CEO on 4 July.

Action required

3. The Authority are asked to note the areas for review and the timetable for delivering revised fees for sign off by the Authority at its November 2019 meeting.

Background

4. The HTA undertook a full review of its fee structure in 2016, this included the construction of a new fees model by external contractors and wide consultation on a number of fee charging options across our establishments.

5. Since this last review we have continued to see restructuring of establishments and their functions across sectors that results in a reduction in the overall level of fees we recover. This has led us to conclude that a review should be undertaken to consider whether the fees structure still reflects the regulatory effort expended across sectors, in particular with regard to different establishment structures.

Process and timetable

6. We have arrived at six areas to consider as part of our review. These are:

    - The overarching fee structure;
    - Charges for satellite sites;
    - Charging for different types of activity undertaken;
    - A proposal to charge for Third Party Agreements;
    - A proposal to introduce a short term/temporary licence;
    - To consider whether charges should be made for returning an establishment to compliance.

7. More detail is contained in the table at the end of this paper, including proposed members of the relevant working groups.

8. For existing fee areas, the groups will consider whether the current fee structure reflects the weighting of regulatory activity now undertaken against the relevant categories. Where there is felt to be an imbalance the working groups will propose revisions to the weighting of fees. This will not, therefore, change the fee structure but the weighting of the fee against existing categories.

9. Where groups are considering the introduction of a new fee or charge the group will consider whether a material amount of regulatory effort is being consumed in the area and the likely behavioural impact on licence holders if a fee were to be introduced.

10. Working groups will provide initial recommendations that will be presented to the Authority at its strategic away day in October. Following this will be a period of consultation, dependent on the materiality of any change proposed, with sectors and/or individual establishments which will lead to papers being presented at Stakeholder and Fees Group and the Audit and Risk Assurance Committee in October.

11. Final proposals on any revision to the fees structure will be presented, as in previous years, for Authority sign off at its November 2019 meeting.

Work Package	Considerations	Working Group	Status
WP1 – Fee structure	- Reduce main fee level and increase activity fee levels? - Introduce TPA's to the fees structure? - Review satellite fees: consider the banding for number of satellites -v- the activity levels of satellites	Finance Manager, Director of Resources, Head of Post Mortem and Public Display, Head of Development, Head of Human Application, Director of Regulatory Delivery.	
WP2 - Satellites	- Size of satellites (activity levels) - Number of satellites that can be linked to a main site - Geographic location of satellites to main site - DI oversight of multiple satellite sites	Finance Manager, Head of Development, Head of Human Application, Head of Research and Anatomy, Head of Post Mortem and Public Display, Director of Regulatory Delivery.	
WP3 – Activities undertaken	- Review weighting of activity levels in HA & PM sectors - Review activities that can be allowed under a licence (research Tissue banks under a HA or PM licence, or End use storage) - Are the activities charged for correct?	Finance Manager, Head of Development, Head of Human Application, Head of Post Mortem and Public Display, Director of Regulatory Delivery.	
WP4 - TPAs	- Should we charge for TPA's? - Can TPA's be grouped / categorised? - Limit number of TPA's held by a licence? - Consider threshold for TPA –v- a satellite?	Finance Manager, Head of Development, Regulation Manager (Human Application), Head of Human Application, Director of Regulatory Delivery.	
WP5 – Temporary licence	- Should we introduce a temporary licence? - Impact on application fee?	Finance Manager, Head of Research and Anatomy, Director of Regulatory Delivery, Regulatory Operations Manager.	
WP6 – Return to compliance	- Should we charge for a delay in establishment returning to compliance? - What would we consider normal return to compliance? - Should fees be flat or tiered?	Finance Manager, Head of Development, Head of Human Application, Head of Post Mortem and Public Display, Head of Research and Anatomy, Director of Regulatory Delivery.	