

## Eighty-eighth Meeting of the Human Tissue Authority

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**Date** 9 May 2019  
**Time** 10.00 – 12.15  
**Venue** Etc Venues  
One Drummond Gate, London SW1V 2QQ

### Agenda

1.	Welcome and apologies	
2.	Declarations of interest	Oral
3.	Minutes of 7 February 2019	HTA (09/19)
4.	Matters arising from 7 February 2019	Oral
<b>Regular Reporting</b>		
5.	Chair's Report	Oral
6.	Chief Executive's Report	HTA (10/19)
7.	Delivery Report – Quarter Four 2018/19	HTA (11/19)
8.	Development Report – Quarter Four 2018/19	HTA (12/19)
9.	Deployment Report – Quarter Four 2018/19	HTA (13/19)
<b>Committee and Advisory Group Reporting</b>		
10.	Audit and Risk Assurance (ARAC)	Oral
11.	Transplant Advisory Group (TAG)	Oral
<b>Policy Issues</b>		
12.	Introduction of Deemed Consent in England	HTA (14/19)
13.	White space for open discussion	Oral
14.	Any other business	Oral

Meeting close: 12.15

## Minutes of the eighty-seventh meeting of the Human Tissue Authority

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<b>Date</b>	7 February 2019
<b>Venue</b>	Viceroy Suite, Grosvenor Hotel, 101 Buckingham Palace Road, London SW1W 0SJ
<b>Protective Marking</b>	OFFICIAL DRAFT

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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. Dame Sally Macintyre  
 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)  
 Nima Sharma (Board Secretary; minute taking)

#### Observers

Jeremy Mean (Department of Health and Social Care)  
 Ruth Joyce (Senior Policy Manager)  
 Rachel MacLehose (Head of Performance and Planning)

Item	Title	Action
Item 1	<b>1. Welcome and apologies</b>	
	1. Bill Horne (the Interim Chair) welcomed Members, attendees and observers to the eighty-seventh meeting of the Human Tissue Authority (HTA). The Chair welcomed	

	<p>back Dr. Abdalla following his recent ill health and also welcomed Nima Sharma to her first meeting in the capacity of Board Secretary.</p> <p>2. There were no apologies received from Members, however Bishop Graham Usher was unable to join at the beginning of the meeting and was only in attendance from 11am onwards.</p>	
<b>Item 2</b>	<b>Declarations of interest- Oral</b>	
	<p>3. The Chair asked Members if they had any personal or pecuniary interests to declare in relation to items of the meeting's agenda; none were declared.</p>	
<b>Item 3</b>	<b>Minutes of 8 November 2018 meeting-</b>	
	<p>4. The Chair requested members to comment on the minutes for accuracy.</p> <p>5. The following clarifications were made:</p> <ul style="list-style-type: none"> <li>• Richard Sydee provided clarification in relation to paragraph 96 confirming that the use of the titles 'resource' and 'capital funds' was correct.</li> <li>• Members agreed that paragraph 116 should be amended to 'Members approved the paper and its recommendations'.</li> </ul> <p>6. Following the above amendments the minutes were accepted as an accurate record of the meeting.</p>	
<b>Item 4</b>	<b>Matters arising from 8 November 2018 meeting</b>	
	<p>7. The Chair noted that all actions from the 8 November 2018 Authority meeting were resolved, ongoing in nature or would be addressed by the Senior Management Team (SMT) during the meeting.</p> <p>8. The Chair confirmed that all matters arising were circulated prior to this meeting along with the dates for the upcoming Authority meetings.</p> <p>9. The following updates were noted during the meeting:</p>	

- Nicky Harrison noted that training on enquiries had been provided to colleagues across Regulation Directorate as part of a broader set of training covered at the recent Regulation Training Day, with some of the session being dedicated to the enquiries project.
- Richard Sydee provided an update about the remote workspace and informed members that this remains as work in progress. He confirmed that it is unlikely and difficult for documents to be managed offline.
- Dr Hazel Lofty provided an update about Member training sessions. Suggestions from Authority members had been taken into consideration. Dr Hazel Lofty asked members if they find the training useful and to provide their suggestions directly to herself or send these to the Board Secretary email address.
- Following the rationale of the afternoon training sessions being queried, members agreed it would be beneficial for the Senior Management Team and the Authority to address training needs collaboratively to ensure that training delivered met the training needs of the Board. Members also felt that sector specific training was useful as not all Authority members have the knowledge of each sector.
- Members also suggested that training could be more helpful for new Authority members as part of their induction to the role and to use the term 'seminar' as oppose to 'training'.
- Members agreed that training from Regulation Managers leading inspections would be invaluable and that attending inspections in an observer capacity is very informative.
- Members highlighted concerns surrounding information being sent and copied to their personal email accounts as opposed to HTA email accounts and the risk of not receiving important information to the correct account. It was agreed that the Executive would need to ensure that all emails are sent to the HTA email accounts.

**Action 1: Dr Hazel Lofty to review the functioning of the email**

	<p><b>accounts and why emails are forwarded to personal email accounts. Members to be notified of the date by which this issue will be resolved.</b></p>	
<b>Item 5</b>	<b>Chair's Report- Oral</b>	
	<p>10. The Chair provided an oral report and opened by wishing Professor Dame Sally Macintyre all the best for the future owing to her impending departure from the HTA. The Chair also extended his congratulations to Nicola Blackwood, the previous HTA Chair, on her appointment to House of Lords and expressed his thanks for her significant contribution to the HTA whilst in post.</p> <p>11. The Chair informed Members that, with the agreement of the department, he will be working from home predominantly and is hopeful that a new permanent appointment of a HTA Chair will be made soon.</p> <p>12. Efforts to appoint a new HTA Chair are underway and members will be updated as they progress. Jeremy Mean suggested that the appointment of new members might be delayed until a new Chair was in place. Members were firm in their view that appointments to the Authority member posts should not be delayed by the chairs process.</p> <p>13. The Chair updated Members on the British Transplant Games launch in Newport, which he attended in January.</p> <p>14. Members were also updated on the parliamentary progress of the Organ Donation Bill.</p> <p>15. The Chair also informed Members that NHSBT were to host the 20<sup>th</sup> European Organ Donation day, with support from the HTA, in October 2019. The Chair requested for Members to confirm if they would like to attend this.</p> <p>16. The Chair thanked everyone for their efforts in ensuring the success of the November HTA Conference.</p> <p>17. Finally, the Chair thanked Betty Lamport, Executive Assistant to the Chair, CEO and SMT for her support and hard work as she is retiring from her post after 12 years of</p>	

	<p>service. The Chair reminded Members to send all future correspondence to Dr Hazel Lofty or to the Board Secretary email address.</p> <p><b>Action 2: Jeremy Mean to commence campaign to recruit new Authority member.</b></p>	
<b>Item 6</b>	<b>Chief Executive's Report [HTA 02/19]</b>	
	<p>18. Allan Marriott- Smith presented this item and introduced this report.</p> <p>19. Members were informed that all five strategic risks remained stable along with staff attrition rates, however, three posts remained unfilled at the end of January 2019 and were being redesigned to meet future capability needs.</p> <p>20. Members were provided with an update about the Transformation Programme. Allan Marriott-Smith emphasised the importance of engaging staff within the programme for this to be a success.</p> <p>21. The Executive has identified new strategic risks to the delivery of this programme and a deep dive will be carried out by ARAC during the February 2019 meeting.</p> <p>22. Members were informed that there are a few core aspects to the delivery of the Transformation programme which are:</p> <ul style="list-style-type: none"> <li>• Management and leadership;</li> <li>• Emerging risks around information governance;</li> <li>• Capability.</li> </ul> <p>23. Members were notified that the Remuneration Committee met in December and agreed the arrangements for senior staff pay awards for 2018. The Committee agreed to make a consolidated pay increase of 1.5% for eligible senior managers. This is the same as the consolidated award made to all other staff. The Committee also agreed to make a non-consolidated award to one senior manager in line with the recommendation set out in the DHSC senior pay</p>	

	<p>guidance.</p> <p>24. Members were updated on the GDPR internal audit where the HTA had achieved moderate assurance. The Chair thanked ARAC and the Executive for their hard work to reach GDPR compliance whilst acknowledging further work would be required</p> <p>25. Allan Marriott-Smith informed Members that the HTA is actively engaging with faith groups about the Organ Donation (Deemed Consent) Bill. Members were informed that the HTA had met with two groups so far.</p> <p>26. Members were further updated on the proposal to set up a taphonomy facility in the UK. Members agreed that it is important for the HTA to agree a position on this and the Policy Manager who is on secondment will be taking this piece of work forward. Professor Penney Lewis agreed that this project is not fully scoped and requires further work.</p> <p>27. Dr Hazel Lofty provided a further update on recent activity involving a commercial service requiring removal of tissue from the deceased at a funeral director premises. Members were informed that the discussion is ongoing and the HTA will continue to engage with this service provider to provide appropriate advice.</p> <p>28. The Authority noted the content of the report.</p> <p><b>Action 3: Richard Sydee to provide the internal GDPR compliance audit report to be shared with Members.</b></p>	
<b>Item 7</b>	<b>Delivery Report- Quarter three 2018/19 [HTA 03/19]</b>	
	<p>29. Nicky Harrison presented this item and introduced the report.</p> <p>30. Members were advised that the KPI summary at the beginning of the Delivery Report shows that regulatory delivery has stayed on track over quarter three. However, the 10 day turnaround time to answer enquiries has been missed as some enquiries have been closed just after the</p>	

10 day turnaround. Members were also informed that some enquiries can be quite complex and challenging to answer.

31. Professor Dame Sally Macintyre suggested whether the KPI for answering enquiries could be changed so that the targets are more achievable, for example 95% of enquiries are answered within 10 days and 100% are answered in 15 days. The chair whilst sympathising with that view, reported that the executive were focussed on seeing an improvement in performance in this area and so the KPI would remain as it stands for the time being.

32. Members had previously questioned whether enquiries could be better managed electronically, which may help to alleviate pressure on staff. Members also suggested that improving accessibility to information on the HTA's website could help to reduce the number of enquiries received. Dr Hazel Lofty reassured the Authority that the Executive is undertaking work to streamline the way in which enquiries are handled.

33. Nicky Harrison confirmed that KPI 4 which is about timely completion of major and critical CAPAs was at its lowest, with the performance target for December being at 42%.

34. Nicky Harrison highlighted to Members that there may be a need to discuss a more appropriate way of addressing CAPAs as deadlines can be narrowly missed due to the workload. Nicky added that the Transformation programme will enable the HTA to review its approach to CAPAs and also improve the staff induction programme. Rachel MacLehose, Head of Planning and Performance will be looking at how to collect data for the delivery report more effectively.

35. Amanda Gibbon questioned whether there is a process of escalation if a CAPA is complex. Nicky Harrison confirmed that there is a process in place to manage complex CAPAs.

36. Dr Stuart Dollow enquired whether there is any forewarning about whether staff are meeting the KPIs and whether there should be a mechanism to check in with staff to see if there could be delays to the resolution of CAPAs.

	<p>37. Members raised their concerns about the number of HTARIs in the PM sector which are due to human error. Members discussed whether more advice and guidance should be provided to the sector to help reduce the number of incidents.</p> <p>38. The Authority noted the content of the report.</p>	
<b>Item 8</b>	<b>Development Report- Quarter three 2018/19 [HTA 04/19]</b>	
	<p>39. Dr Hazel Lofty presented this item and introduced the report.</p> <p>40. Dr Hazel Lofty informed members that the Annual conference went very well and that the Public Authority meeting will take place in May 2019.</p> <p>41. Members were informed that residual CRM system changes have been scoped but will not be deployed until the CRM upgrade work is completed in February 2019. Dr Lofty informed Members that training will be provided in due course.</p> <p>42. The blog functioning on the HTA's website has been commissioned and goes live in quarter 4 and should help to improve engagement. During the meeting, Dr Lofty asked Members to confirm if they would like to provide material for the BLOG to send this across to her directly.</p> <p>43. Members were informed that there will be a continuous system for IA accreditation. Members noted that IA reports are sometimes lacking detail and feel that there is a need to standardise the approach that IAs take when completing their reports. Dr Hazel Lofty confirmed to Members that she will relay this to Dr Chitvan Amin, Transplant Manager to take forward.</p> <p>44. Members were advised that progress was ongoing with the Independent Assessors (IA) Sustainability project. At present work has been carried out to develop a code of conduct for IAs to sign which is currently undergoing legal</p>	

	<p>review to establish whether the HTA can insist that IAs sign this document. There has been no feedback yet. The HTA would like to make the role more formal, however, any changes made must be reasonable.</p> <p>45. Dr Hazel Lofty informed Members that work is ongoing to review the use of organ perfusion devices in the UK. Based on the outcome from audits carried out in the ODT sector as well as ODT SAEARs reported to the HTA by NHSBT, there is a greater use of warm perfusion machines. The HTA requires better oversight of this particular area and moving forward aims to develop a policy around this.</p> <p>46. The Authority noted the content of this paper.</p> <p><b>Action 4: Dr Hazel Lofty to relay information regarding IA reports to Dr Chitvan Amin.</b></p> <p><b>Action 5: Members to be provided with updates about the IA Code of Conduct following legal review.</b></p> <p><b>Action 6: Dr Hazel Lofty to organise CRM training for Members once CRM upgrade is complete.</b></p>	
<b>Item 9</b>	<b>Deployment Report- Quarter three 2018/19 [HTA 05/19]</b>	
	<p>47. Richard Sydee presented this item and introduced the report.</p> <p>48. Richard Sydee informed Members that there has been an intake of new staff as well as consideration of more flexible working arrangements.</p> <p>49. Members were informed that three Senior Regulation Manager posts were advertised and one successful appointment made to the Senior Policy Manager post. The post of Senior Regulation Manager for the Post Mortem sector has not been filled and will await the new Head of Regulation, Post-Mortem sector to return to take this forward. Unfortunately a successful appointment to the Senior Regulation Manager for Human Application was not made and this role will need to be reviewed.</p>	

	<p>50. Members were informed that recruitment is being undertaken for a Digital Communications Manager which is a new role. In addition, a Business Support Manager role has been created to support the day to day management of the office.</p> <p>51. Members were notified that there is one vacant RM post and a number of other roles that are being scoped by the HTA, for example, a Business Change Manager role, a Information Records Manager and a Regulatory Training Development Manager.</p> <p>52. Richard Sydee confirmed that there had been an under spend this quarter and that the HTA has received some additional funding relating to depreciation costs which the Department of Health and Social Care have asked to review. Members were informed that there was a £30k deficit against budgeted licence fee income and although it was a significant amount, there is no cause for concern. This was due to companies in the HA sector not paying their licensing fees on time.</p> <p>53. Members were informed that all new IT equipment has now been rolled out, however there are some issues relating to skype which are ongoing. Martin Cranfield has returned to the HTA on a part time basis to provide IT support. Members were advised that the HTA has filled the BCC IT position with a very experienced member of staff which will enable David Thomson, Head of Business Technology, to be more involved in the HTA's strategic planning.</p> <p>54. The Authority noted the content of this paper.</p>	
<b>Item 10</b>	<b>Histopathology Working Group [Oral]</b>	
	<p>55. Dr Lorna Williamson provided an oral update on matters arising at the last Histopathology Working Group.</p> <p>56. Dr Lorna Williamson informed Members that the main area of concern discussed at the meeting was about the reduction in compliance with HTA standards evidenced by an increase HTARIs and shortfalls identified following</p>	

inspections.

57. Members were told that there has been a reduction in the number of critical shortfalls identified during Post-Mortem inspections. However, the main issue appears to be related to lack of traceability. Dr Lorna Williamson further advised that lack of governance remains an issue and may be due to an increase in the number of NHS Trusts forming Pathology networks.

58. Members noted that it is crucial for training to be maintained for staff involved in the hospital post-mortem consent seeking process.

59. Members were informed that there is a need for Mortuaries to use three points of identification to prevent incidents occurring due to human error and that there is a lack of pathologists to undertake Post-Mortem examinations.

60. Members were told that the mishandling of blocks and slides would be included in the current HTARI categories.

61. Members were advised that non-invasive Post-Mortems through CT scanning is being used increasingly amongst certain faith groups. There is guidance being developed about this, however, the HTA does not licence this activity. Members agreed that the HTA should maintain oversight of this guidance and undertake a review to ensure that it contains appropriate information.

62. It was highlighted to Members that the Histopathology Working Group will be developing a new guidance document to communicate to the sector to help strengthen governance and mitigate the risk of incidents occurring and increase compliance with HTA standards.

63. Members were informed about the HTA's position with regards to removal of relevant material from the deceased following needle stick injury to a member of staff during a Post-Mortem examination. Coroners are in a position to mandate tissue to be removed to establish cause of death under coronial legislation, however, cannot authorise the removal of samples for reasons outside this. There is legal

	<p>precedent for a Judge allowing removal of samples for health protection purposes, but that this is not something that is permitted under current legislation without permission from a court in each individual circumstance.</p> <p>64. Members were told that there is a shortage of Pathologist in Northern Ireland and as a result perinatal Post-Mortem examinations are now taking place at Alder Hey Children's Hospital.</p> <p>65. On a general note, Professor Andy Hall commented that the organogram provided for the Histopathology Working Group should be included in every paper or sent to all Authority members.</p> <p>66. Members were also updated on developments connected with Medical Examiners and forensic recovery by police at the scene of unexplained deaths at home.</p> <p>67. The Authority noted the content of this report.</p> <p><b>Action 7: The HTA's organogram to be circulated to Authority Members.</b></p>	
<b>Item 11</b>	<b>Code of Practice for Deemed Consent England [Oral]</b>	
	<p>68. Dr Hazel Lofty introduced this paper and provided Members with an update on the legislation and on progress with amending the Code of Practice, F, in preparation for the introduction of deemed consent in England. Dr Hazel Lofty thanked Dr Chitvan Amin for her contribution in amending Code F.</p> <p>69. Dr Hazel Lofty informed Members that there have been three or four proposed amendments, however the Bill has passed without any changes. Jeremy Mean confirmed to Members that the final stage will be the third reading and any amendments at this stage will be unlikely. Dr Hazel Lofty thanked Jeremy Mean and his team for their support.</p> <p>70. Dr Hazel Lofty informed Members that the amended Code F will be structured in three sections. It was highlighted to Members that there is an algorithm/flow chart which will act</p>	

to inform practitioners on the processes to be followed.

71. Members were asked to provide preliminary feedback about their thoughts on the changes made to Code F. Members agreed with the changes that have been made so far and raised a number of points to clarify their understanding of the changes made.

72. Members discussed what would happen if the family of the deceased objected to organ donation and how this could leave professionals in a difficult position. Members were informed that the decision to proceed with organ donation will be determined by the clinician on the basis of whether the individual expressed an opinion about donation. In the absence of this information, deemed consent may be considered by the clinician where the individual has not made a decision on organ and tissue donation or appointed a nominated representative. The deemed consent legislation does not mandate that organ donation goes ahead in these cases. Members noted that the deemed consent legislation has many parallels with the current system of organ donation in England.

73. Members agreed that Code F require further review. Members also recommended that Paragraph 162 should define that a child is under the age of 18 years.

74. A number of points were raised by Members during the meeting, such as; the applicability of the code in relation to the jurisdiction in which a person dies and how the code applies to Armed Forces deployed in another country.

75. Members agreed that communication with the public about deemed consent is vital, as there may be strong opposition from people who actively opt out. Dr Hazel Lofty informed Members that she sits on the programme board for the publicity campaign. Members agreed that it is important for the HTA to have input into the direction of the campaign.

76. Members were informed that a meeting was due to be held on the 25 February 2019 with Faith Leaders about deemed consent and were invited to attend in they wished Members reflected on the communication campaign that was

	<p>undertaken in Wales in relation to the opt- out system in Wales and agreed that a similar approach would need to be taken in England.</p> <p>77. The Authority noted the content of this report.</p> <p><b>Action 8: Dr Hazel Lofty to make changes to the Code of Practice in line with the recommendations made during the meeting.</b></p>	
<b>Item 12</b>	<b>HTA Strategy 2019-2022 [HTA 07/19]</b>	
	<p>78. Dr Hazel Lofty presented this paper.</p> <p>79. Members were informed that there are three documents for members to provide their comments, including the Overarching strategy document, the People strategy and the Digital strategy. Dr Hazel Lofty informed Members that they should be familiar with the Rolling Strategic plan and welcomed any feedback or comments in relation to the paper.</p> <p>80. Glenn Houston commented that the document was well written and suggested that the page numbers be added.</p> <p>81. Amanda Gibbon suggested that the Authority should have a copy of the suite of KPIs to help demonstrate how the HTA is delivering against its strategy.</p> <p>82. Members commented that without milestones it would be difficult to monitor progress with KPI:7 which is to further plan, develop and implement an organisational transformation programme.</p> <p>83. Dr Hazel Lofty welcomed feedback on the Digital strategy document and emphasised that it is a key area to achieve the HTA's aims. Glenn Houston commented that this document was also well written and suggested adding information about the costs of undertaking the digital improvement.</p> <p>84. Allan Marriott-Smith presented the People Strategy and informed Members that the shape of the document remains</p>	

	<p>the same. Members were informed that particular sections of the document have changed to reflect the HTA's commitment to the transformation programme.</p> <p>85. Glenn Houston advised that the reference to pay constraints should be removed from the body of the text as this is not relevant.</p> <p>86. Amanda Gibbon felt that the document was well written and commented on the importance of face to face meetings and how they should be encouraged amongst staff. Dr Hazel Lofty agreed that it is important for staff to meet face to face, particularly for appraisals or important meetings. Dr Hazel Lofty confirmed that there is an All Staff Away day in March where this will be covered.</p> <p>87. Members agreed to approve the Overall strategy, the People strategy and the Digital strategy.</p> <p><b>Action 9: Allan Marriott-Smith to amend document to ensure that reference to pay constraints is removed.</b></p> <p><b>Action 10: Dr Hazel Lofty to add page numbers to the Rolling Strategic Plan.</b></p> <p><b>Action 11: SMT to provide Members with a list of KPIs.</b></p>	
<b>Item 13</b>	<b>Authority Standing Orders Update [HTA 08/19]</b>	
	<p>88. Dr Hazel Lofty presented this paper.</p> <p>89. Members were asked to approve the amendments proposed to the Authority's Standing Orders regarding minor amendments to the Audit Risk and Assurance Committees terms of reference document.</p> <p>90. The Authority approved the document.</p>	
<b>Item 13</b>	<b>Any Other Business [Oral]</b>	
	<p>91. The Chair informed Members that an updated version of the HTA's expenses policy was circulated in advance of the meeting and will come into effect from April 2019.</p>	

92. Members were informed that a cap applies to the cost of accommodation if a HTA staff member chooses to book their own accommodation.
93. Graham Usher highlighted the importance of booking the most cost effective train tickets as on occasions he had found these but had then been issued with more expensive open returns.
94. Professor Dame Sally Macintyre considers the use of overnight sleepers to be considerably cheaper and cost effective and something that should be explored further.
95. Professor Andy Hall questioned whether it would be possible to arrange authority meetings so that they fall on consecutive days to reduce costs and where possible to avoid situations where members are travelling to London on consecutive weeks.
96. No other business was raised.

## Authority paper

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**Date** 9 May 2019 **Paper reference** HTA (10/19)

**Agenda item** 6 **Author** Allan Marriott-Smith

**Protective Marking** OFFICIAL

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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 between the last Authority meeting on February 2018 and the end of May 2019, which are not reported elsewhere.

### Decision-making to date

2. This report was approved by the CEO on 29 April for submission to the Authority.

### Action required

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

### Overview of strategic risks

4. In its April assessment of the six strategic risks (found in **Annex A**), SMT were of the view that there was upward pressure on risk 3 *Failure to manage expectations of regulation* and risk 4 *Failure to utilise our capabilities effectively* for the reasons identified on the summary page of the Annex.

## **Other issues**

### HTA transformation programme

5. At its meeting in February, the Audit and Risk Assurance Committee (ARAC) undertook a deep dive on the emerging plans for the HTA transformation programme. There will be a report on this at item 10 of the May Authority meeting.
6. In March, the HTA engaged external consultancy advice to assist in the programme design. Specifically:
  - options for high-level programme design, building on the work already commenced by HTA staff;
  - a proposal for programme governance arrangements that are appropriate to the HTA's size, and which utilise, where possible, existing governance arrangements;
  - an assessment of the minimum skill set that would be required in house to manage the programme effectively and to maximise the chances of delivering the anticipated business change and benefits.
7. This work has now been completed and the recommendations will be adopted, as necessary, as the change work commences in the coming year.

### Accountability to the Department of Health and Social Care

8. The HTA met with DHSC on 2 May 2019 as part of its regular quarterly accountability meetings for and end of year review.
9. An oral update on the outcomes of the meeting will be provided at the meeting.
10. Minutes of the January 2019 accountability meeting have been circulated with the Authority papers for information.

### Authority appointments

11. The competition to recruit a new permanent Chair of the HTA was launched on 28 March. Interviews are planned for 14 May with an appointment anticipated with Secretary of State approval shortly thereafter.
12. The competition to recruit a two new HTA Members was also launched on 28 March. Interviews are planned for 28 June.

All staff away day

13. An all-staff away day took place on Monday 18 March 2019. As well as providing a refresher on the annual Personal Development Plan (PDP) review process and the 2019/20 business plan, there were a number of interactive sessions with staff focussing on various aspects of the new People Strategy. Specifically:
- an outline of the likely changes to the HTA pay framework and the indicative timings for further consultation.
  - the latest developments with regard to the office move.
  - the Identification of good practice in smart working to inform the HTA's policy and guidance on remote and flexible working.
14. The morning generated a lot of useful discussion and a large number of questions which are being addressed as part of ongoing management of change within the HTA.

Consultation on coronial investigations of stillbirths

15. On the 26 March 2019, the government launched a [consultation](#) on proposals to give coroners the power to investigate full-term stillbirths to help provide parents with vital information on what went wrong and why, while ensuring any mistakes are identified to prevent future deaths. The consultation from the MoJ and DHSC will run for 12 weeks, closing on 18 June 2019.
16. Currently coroners can only hold inquests for babies where it is suspected, or have showed signs of life following birth. The proposed system will:
- give coroners powers to investigate full-term stillbirths occurring from 37 weeks of pregnancy;
  - allow coroners to consider whether any lessons can be learned, helping to prevent future stillbirths;
  - mean coroner's will not have to gain permission or consent from any third party in exercising this power; and
  - not replace current investigations undertaken by the hospital or NHS agencies.
17. The HTA is in the process of reviewing the full consultation, including any potential interaction with the HT Act and the information in the Codes of Practice, and will be providing a considered response to the consultation by the deadline.

GDPR compliance

18. SMT has spent considerable management time on ensuring full GDPR compliance. An update was provided to ARAC in October which concluded that full compliance would

be achieved by the end of March 2019. This was achieved, with the exception of the procurement of a new personnel records management system, which is still in train.

19. An internal audit on GDPR compliance was undertaken in March and provided moderate assurance overall. Moderate is defined as 'some improvements are required to enhance the adequacy and effectiveness of the framework of governance, risk management and control'. The report made three medium priority recommendations for further work.

#### Complaints

20. The HTA received two complaints in quarter four, one of which was dealt with formally, and the other informally. In addition, a reconsideration of a Freedom of Information (FOI) request decision was managed under the complaints process (as required by the HTA FOI policy).

## HTA Strategic Risk Register April 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. Recruitment for Regulation Managers has been successful with only one RM post vacant at the start of April.

**Other notable risks:** Uncertainty posed by EU Exit, which is largely dependent on outcomes of the ongoing negotiations and resource dedicated to 'no-deal' planning which impacts on other work. The recently created Head of Planning and Performance role is once again vacant, which will impact on our resource and business planning (R6). We are also recruiting for a permanent replacement for our Head of HR. During recent recruitment rounds we have experienced high levels of drop out for candidates invited to interview as well as poor quality applications. 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. DHSC spending controls are likely to place continuing pressures on ALBs to make savings.

Risk	Jan 2019	Feb 2019	Mar 2019	Apr 2019	Comments
<b>1 - Failure to regulate appropriately</b> (Risk to Delivery a-d & f and Development a-d)	→	→	→	→	A good regulatory framework and processes are in place and continuous improvement is planned. It is important to identify changes and remain agile to adapt to these. A number of new Regulation Managers have increased the organisation's capacity and strengthened our regulatory capability. Recent recruitment has resulted in all but one Regulation Manager posts being filled. Recruitment for other vacancies is ongoing and despite seeing high levels of candidate drop out at interview stage, we have been successful in our recent recruit rounds so that, for example, our new Transplant Officer will take up post shortly before the departing Transplant Officer leaves. The development of a revised induction programme for RMs is progressing well but a review of Standard Operating Procedures is required in order to achieve consistency with consistent training in up to date practice. A training session with RMs on CAPA management and procedures to facilitate consistency have recently taken place. We recognise that there has been an issue with the speed at which new RMs are being inducted which is related to the pressure on existing staff who not only maintain BAU but are involved in other projects. We are actively working to address this and have maintained the risk level. Recent churn amongst the Authority, including the Chair, leaves potential gaps in oversight and support on upcoming regulatory and transformation issues.
<b>2 - Failure to manage an incident</b> (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.
<b>3 - Failure to manage expectations of regulation</b> (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.
<b>4 - Failure to utilise our capabilities effectively</b> (Delivery a-e) (Development a-d) (Deployment a, c and d)	→	→	↑	↑	We continue to be in a position 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.
<b>5 - Insufficient, or ineffective management of, financial resources</b> (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.
<b>6 - Failure to achieve the benefits of the organisational transformation programme</b> (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.

**Strategic Objectives**

**Delivery objectives**

- Deliver a right touch programme of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.
- Deliver effective regulation of living donation.
- Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit.
- Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards.
- Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.

**Development objectives**

- Use data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target resources effectively.
- Make continuous improvements to systems and processes to minimise waste or duplicated effort, or address areas of risk.
- Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements.
- Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

**Deployment objectives**

- Manage and develop our people in line with the HTA's People Strategy
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- Provide a suitable working environment and effective business technology, with due regard for data protection and information security
- Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation

Risks are assessed by using the grid below

Risk scoring matrix						
Impact	5. Very High	5	10	15	20	25
	4. High	4	8	12	16	20
	3. Medium	3	6	9	12	15
	2. Low	2	4	6	8	10
	1. Very Low	1	2	3	4	5
	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



REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
2	<p><b>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</b></p> <ul style="list-style-type: none"> <li>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)</li> <li>caused by deficiency in the HTA's regulation or operation</li> <li>where we need to regulate, such as with emergency mortuaries</li> <li>that causes business continuity issues</li> </ul> <p><b>(Risk to all Delivery Development and Deployment objectives)</b></p> <p>Risk owner: <b>Nicky Harrison</b></p>	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</li> <li>Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)</li> <li>Failure to work effectively with partners/other organisations</li> <li>Breach of data security</li> <li>IT failure or attack incident affecting access to HTA office</li> <li>Consequences of 'no-deal' EU Exit affecting supply routes, staff availability or multiple incidents</li> </ul> <p><b>Effect</b></p> <ul style="list-style-type: none"> <li>Loss of public confidence</li> <li>Reputational damage</li> <li>Legal action against the HTA</li> <li>Intervention by sponsor</li> </ul>	5	3	Future, should event occur	<ul style="list-style-type: none"> <li>Filled identified business-critical roles</li> <li>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</li> <li>Media handling policy and guidance in place, including regular media training for key staff &amp; Members with relevant scenarios, to supplement media release and enquiries SOPs</li> <li>Accessible lines to take and key messages for likely scenarios</li> <li>Availability of legal advice</li> <li>Fit for purpose Police Referrals Policy</li> <li>Onward delegation scheme and decision making framework agreed by the Authority</li> <li>Regulatory decision making framework</li> <li>IT security controls and information risk management</li> <li>Critical incident response plan regularly reviewed and tested</li> <li>Evaluate test exercise of incident and feedback to all staff.</li> <li>Plan to develop and strengthen the relationship with DIs</li> <li>EU exit plans in place</li> </ul>	3	2		X			Preventative	Monthly reports to HTAMG	Last report December 2018
									X	X		Preventative	Policies etc. reviewed annually, training specification and notes after incident reviews	Reviewed by ARAC October 2018	
									X			Preventative	Policy reviewed annually, training specifications Reports on media issues in Delivery Report	Media policy to be reviewed.	
									X			Preventative	Documented, incidents reported to Chair and in Delivery Report	Delivery report to Authority meeting November 2018	
									X			Preventative	Lawyers specified in Critical Incident Response Plan, SMT updates	In place	
									X			Preventative	Annual review of policy (minimum), usage recorded in SMT minutes	Policy reviewed by Authority July 2018	
									X	X		Preventative	Standing Orders and Authority minutes	SO reviewed and agreed in 4 May 2017 (next review May 2019)	
									X			Preventative	Reports to Authority of key decisions in Delivery Report	Satisfactory reports made in November 2018	
									X	X		All	SIRO annual review and report Internal audit reports	Cyber security review - agenda item at ARAC June 2018	
									X	X		Preventative	Critical Incident Response Plan and notes of test, reported to SMT	CIP was used to manage a power outage during March 2018 and a regulatory incident arising in April 2018	
									X			Preventative		Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018	
									X			Preventative	Blog and DI training	Project on business plan	
													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.	





REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT RISK PRIORITY		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL RISK PRIORITY		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
5	<p><i>Insufficient, or ineffective management of, financial resources</i></p> <p><i>(Risk to Deployment objective b</i></p> <p><i>Risk Owner:</i></p> <p><i>Richard Sydee</i></p>	<p><b>Cause</b></p> <ul style="list-style-type: none"> <li>• <i>Fee payers unable to pay licence fees</i></li> <li>• <i>The number of licenced establishments changes, leading to reduced fee income</i></li> <li>• <i>Management fail to set licence fees at a level that recover sufficient income to meet resource requirements</i></li> <li>• <i>Failure to estimate resource required to meet our regulatory activity</i></li> <li>• <i>Poor budget and/or cash-flow management</i></li> <li>• <i>Unexpected increases in regulatory responsibilities</i></li> <li>• <i>Unforeseeable price increases / reductions in GIA</i></li> </ul> <p><b>Effect</b></p> <ul style="list-style-type: none"> <li>• <i>Payments to suppliers and/or staff delayed</i></li> <li>• <i>Compensatory reductions in staff and other expenditure budgets</i></li> <li>• <i>Increased licence fees</i></li> <li>• <i>Requests for further public funding</i></li> <li>• <i>Draw on reserves</i></li> </ul> <p><i>Leading to:</i></p> <ul style="list-style-type: none"> <li>• <i>Inability to deliver operations and carry out statutory remit</i></li> <li>• <i>Reputational damage and non payment of fees</i></li> </ul>	5	4	Ongoing	Budget management framework to control and review spend and take early action	2	3		X	X		All	Budgetary control policy reviewed annually and agreed by SMT	Last review January 2019
						Financial projections, cash flow forecasting and monitoring			X			Monitoring	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report January 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 November 2018	
						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 April 2018	
						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) <b>Ongoing</b>					X	Detective	Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH	Last quarterly report January 2019	
						Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) <b>Ongoing</b>			X	X		Detective	Quarterly Finance Directors and Accountability meetings	Last FDs meeting Nov 2017. DoF wider network January 2019	

REF	RISK/RISK OWNER	CAUSE AND EFFECTS	INHERENT		PROXIMITY	EXISTING CONTROLS/MITIGATIONS	RESIDUAL		ACTIONS TO IMPROVE MITIGATION	LINE OF DEFENCE			TYPE OF CONTROL	ASSURANCE OVER CONTROL	ASSURED POSITION
			I	L			I	L		1	2	3			
6	<b>Failure to achieve the benefits of the organisational transformation programme</b>  (Development objectives a-d)	<b>Causes</b> <ul style="list-style-type: none"> <li>Programme and project benefits poorly defined and understood</li> <li>Inadequate programme and project governance arrangements</li> <li>Poorly specified programme and projects</li> <li>Insufficient programme, project and change management skills</li> <li>Inadequate leadership of change</li> <li>Inability to access the necessary skills required at a affordable cost</li> <li>Lack of staff buy-in to change</li> <li>Management and Head stretch of delivering transformation alongside business as usual and other development activity</li> <li>Insufficient agility in (re)deploying people to change projects</li> <li>Poorly specified procurement and inadequate contract management</li> <li>Realisation of single points of failure for DDAT and People Strategy</li> </ul> <b>Effects</b> <ul style="list-style-type: none"> <li>Wasted public money</li> <li>Failure to achieve the central strategic intent of the Authority</li> <li>Distracts senior management from operations at a time when demands have increased .</li> <li>Reputational damage</li> <li>Unaffordable cost over run</li> <li>Staff demotivation</li> <li>Data remains under-utilised</li> <li>Technology inadequate to meet future needs (cost, functionality)</li> </ul>	5	4			5	1		1	2	3			
										X			Preventative		
										X			Preventative		
										X			Preventative		
										X			Preventative		
										X			Preventative		
											X		Monitoring		
										X			Preventative		
										X			Preventative		
										X			Preventative		
											X		Monitoring		
										X			Preventative		
										X			Preventative		
										X			Preventative		
											X		Monitoring		
												X	Monitoring/ Detective		
												X	Preventative		

## Authority Report

Delivery – Quarter 4 2018/19

<b>Date</b>	9 May 2019	<b>Paper Reference</b>	HTA (11/19)
<b>Agenda Item</b>	7	<b>Author</b>	Nicolette Harrison
<b>Protective Marking</b>	OFFICIAL	<b>Author Contact</b> Nicolette.harrison@hta.gov.uk	
<b>Strategic objectives</b> (Delivery)	<ul style="list-style-type: none"> <li>a. Deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to public confidence.</li> <li>b. 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.</li> <li>c. Deliver effective regulation of living donation.</li> <li>d. Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us.</li> <li>e. Maintain our strategic relationships with other regulators operating in the health sector.</li> </ul>		
<b>Relevant key performance indicators (KPIs)</b> (marked as red, amber, green, black or blue)	<ul style="list-style-type: none"> <li>1. 200 site visits to take place during the business year across all sectors (year-to-date)</li> <li>2. Report provided to the Authority annually (Q2) on the outcomes of our regulatory interventions and the impact on patient safety and public confidence</li> <li>3. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)</li> <li>4. 100% of Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented (reported monthly) [See KPI narrative on page 10]</li> <li>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)</li> <li>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)</li> </ul>		
<b>Related Strategic Risks</b> (marked as red, amber or green)	<ul style="list-style-type: none"> <li>1 Failure to regulate appropriately (Objectives A-C &amp; E)</li> <li>2 Failure to manage an incident (All objectives)</li> <li>3 Failure to manage expectations of regulation (Objective D)</li> <li>4 Failure to utilise our capabilities effectively (Objectives A-D)</li> </ul> <p>(see paper HTA 10a/19 for detailed information)</p>		

## **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 considered by the Senior Management Team (SMT) at its meeting on 25 April 2019.

## **Action required**

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

## **Directors' summary**

5. Key performance indicators show a clear pattern of consistently strong delivery over this final quarter of the year. It is particularly satisfying to see the improvement made in responding to enquiries within the target deadline. It is also pleasing to note that a full inspection schedule was maintained, enabling the HTA to continue its strong focus on frontline assurance activity and to achieve the targeted 200 site visits for the year.
6. We maintained a strong cadre of staff on Regulatory Delivery in this final quarter, with a full complement of Regulation Managers (RMs) thanks to the recruitment of one new member of staff at the start of January to replace the RM who left at the end of December. The relatively large cohort of eight new RMs recruited in 2018/19 have all progressed well in their training and induction. We have undertaken some useful work with these new RMs over this last quarter to help us critically evaluate our approach to induction. We also held a very successful Regulation Training Day in early January, which covered a wide range of regulatory matters and generated helpful feedback on how we could improve our approach to training and continuing professional development. I look forward to seeing these ideas taken forward in the new temporary (one-year) roles of Regulation Manager – Training, for which we are now recruiting.
7. Regulatory Delivery staff have dealt with a number of Freedom of Information Act (FOI) requests over the past quarter that have focused on various aspects of Regulatory Delivery. These have raised knowledge and awareness of this important subject and helped colleagues develop relevant skills, including extracting and using our data.

8. The remainder of this report gives an indication of the broad range of regulatory matters in which we have been involved over the past quarter.

### **Critical shortfalls**

9. There were four critical shortfalls found on inspection in quarter four, three within the post-mortem sector, and one in the Human Application sector.
10. The critical shortfall identified within the Human Application sector was a cumulative shortfall arising from concerns about storage arrangements and the impact of inadequate temperature monitoring and appropriate follow-up action following temperature excursions.
11. The critical shortfalls identified within the Post Mortem sector were all cumulative shortfalls arising from concerns about audits, reportable incidents and traceability.

### **Investigations**

#### New investigations

12. There have been two new investigations (04/18 and 05/18) in quarter four.

#### *Investigation 04/18*

13. The HTA has received information about an establishment that may be carrying out licensable activities without a licence and is in the initial stages of investigating this.

#### *Investigation 05/18*

14. Concerns were raised with us about an unlicensed establishment that may have breached the licensing requirements of the Human Tissue Act 2004. Following an investigation, we concluded that there had been no such breach.

#### Update on investigation reported in previous Delivery reports (HTA 03/19)

#### *Investigation 03/18*

15. Following review of the comprehensive information we received in response to our enquiries, we concluded that no regulatory action or further information was required and the investigation was closed.

### **Non-routine site visit inspections**

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

17. There was one CAPA follow-up site visit to one establishment in quarter four. This was within the human application sector.

### **Police referrals**

18. There were no police referrals in quarter four.

### **Legal notices**

19. Legal notices to suspend two licences were issued in this quarter. We did not issue any Directions in quarter four.

### **Regulatory decision meetings**

20. Five regulatory decision meetings (RDM) were held in quarter four, one of which was a CAPA follow up from a previous RDM.
21. The first RDM was convened to consider the need to issue Directions to an establishment in the Human Application sector in light of the postponement of the statutory two-yearly inspection that had been scheduled for March 2019. The possibility of issuing Directions was discussed, as were the options of suspending the licence or requesting the establishment revoke their licence. It was agreed that the establishment should be contacted to assess their willingness to accept the issuing of Directions. Draft Directions were sent to the establishment who confirmed that they were happy to accept them in lieu of an inspection. The Directions will be issued in due course.
22. The second RDM was convened as a CAPA follow up to discuss an extension request to complete the remaining unclosed shortfalls identified on inspection. It was decided that the extensions should be agreed, but should be monitored, with the HTA requiring multiple updates.
23. A third RDM was convened to discuss licensed establishments in the Human Application sector that went into administration in February / March 2018 and subsequently progressed towards liquidation. The establishments have not been operational since they went into administration. The HTA issued legal notices to suspend these licences and will review this after three months.
24. The fourth RDM was convened to discuss the number and severity of shortfalls found at an establishment within the Post Mortem sector. The HTA decided to issue a formal letter (but not Directions) alongside the draft report.
25. The fifth RDM was convened to discuss allegations made against an unlicensed establishment that may have breached the licensing requirements of the Human Tissue Act 2004. An investigation was conducted and numerous items were discussed,

however it was determined that the research work was approved by a Recognised NHS REC, meaning that this fell outside the licensing remit of the HTA and is therefore not a breach of the licensing requirements of the HT Act 2004.

## **Reconsiderations, representations and appeals**

26. No reconsiderations, representations or appeals were considered during quarter four.

## **Enquiries**

### General enquiries

27. During quarter 4, we recorded 639 general enquiries (including body donation) compared to 588 in the previous quarter. The enquiries included:

- a. 205 from members of the public about body donation (57 were received via email or phone, and in the post, and 148 via the website). This compares to 225 in the previous quarter.
- b. 434 about licensing or other areas of our regulatory work, compared with 363 in the previous quarter.

28. Of these enquiries, 323 were received via the website, compared to 358 last quarter. Other enquiries are usually received by phone.

29. The HTA sets itself a KPI of responding to 95 percent of general enquiries in ten working days. Of enquiries received during quarter 4, 96 percent were closed in our case management system within ten working days, compared to 92 percent in the previous quarter. Over quarter 4, 98 percent of enquiries were responded to within twenty working days, with the average time taken in quarter 4 standing at five days. The cases that fell outside ten working days generally tended to involve either concerns raised with us about establishments or more complex regulatory matters.

### Freedom of Information Act (FOIA) requests

30. We had 15 FOIA requests in quarter four, compared to 8 in the previous quarter. We publish FOIA responses on our website.

## **Stakeholder engagement**

### ***Annual activity data collection***

31. In January through to February, we contacted establishments in the HA sector regarding the 2018 annual activity data collection.
32. Following feedback from the 2017 annual activity round of submissions, we collected data through the HTA Portal rather than via a spreadsheet as we did the year before.
33. In addition to the standard data set, we again asked establishments to provide information on tissues and cells procured in, and distributed to/from EU/EEA countries. This data contributes to the DHSC's planning to ensure that tissue and cell supply remains unaffected following the UK's exit from the EU.

### ***IA reaccreditation webinars***

34. We held two webinars in February on the revised IA reaccreditation process. The webinars were comprised of a 20-minute presentation hosted by both the Transplant Manager and the Head of Regulation for ODT; followed by a Q&A opportunity. The presentation covered the main changes to the system, including how each IA report will be assessed and given a clarification status.
35. Just over 50 IAs attended the webinars and we received positive feedback on them in follow up surveys. 100% of survey respondents rated the webinars either 'excellent' or 'good'.
36. Following the webinars, we updated the information available on the new reaccreditation system on the HTA website. We also published a recording of the webinar presentation on the HTA portal for IAs to access in preparation of the new system coming into force.

### ***Deemed consent activity***

37. As part of our work on updating our Codes of Practice A and F in light of the introduction in April 2020 of deemed consent in England, we held a multi-faith and community group roundtable event in February. The purpose of the event was to seek views on how conversations with a donor's relatives can be conducted in the most sensitive manner, taking traditions as well as religious and cultural views into account.
38. The event had 24 external attendees, including representatives from several religious, faith and community groups. In addition, colleagues from NHS Blood and Transplant

(NHSBT), the Welsh NHS, and the Department of Health and Social Care also attended to present.

39. The HTA has been participating in NHSBT's Organ Donation Campaign Advisory Group and Organ Donation Legislation Change meetings, to provide advice and guidance to NHSBT on their public awareness campaign for deemed consent.

#### ***Medical Certificate of Cause of Death (MCCDs) email to the Anatomy sector***

40. In January, we emailed Anatomy sector establishments to remind them of the legal requirements of storing bodies for anatomical examination. The information reiterated that storing bodies for anatomical examination is only lawful if appropriate consent and a MCCD is in place.
41. We also shared this information with coroner groups and key stakeholders in the Post Mortem sector.

#### ***Academy of Medical Sciences – Departure Lounge project***

42. The HTA have been participating in the Academy of Medical Sciences' death and dying public engagement project known as 'The Departure Lounge'. The Departure Lounge will be a pop-up, interactive exhibition space in Lewisham, held in May 2019, where the public can talk openly about death and care for people at the end of life. The open space will be accompanied by a website, events calendar and a series of Ipsos MORI workshops.
43. The HTA attended a Departure Lounge content advisory group meeting in January to advise on the importance of conversations with relatives and loved ones about end of life wishes; particularly around donation and consent. We have also regularly contributed and commented on shared content that will be made available to members of the public in the exhibition space.

#### ***AAPT and HTA mortuary mythbusters***

44. The HTA were approached by Hospice UK in quarter four to create a 'mortuary mythbusters' blog which is a series of FAQs that seek to challenge the public's misconceptions about mortuaries.
45. Rather than develop a series of common questions solely from our perspective, the HTA have teamed up with colleagues at the AAPT to develop a combined set of FAQs that set out a two-pronged insight into common misunderstandings around mortuaries; from the view of mortuary professionals and the regulator.

46. The blog is due to be published on the eHospice website, as well as via the HTA public newsletter and social media in quarter one 2019/20.

### ***EU exit planning***

47. In quarter four, we issued a series of emails and published information on our website on 'no deal' preparation guidance for establishments in the HA and ODT sectors. Further reference to this is made in HTA (12/19).
48. In quarter four, the HTA regularly engaged with ALB and DHSC colleagues in the weekly EU exit communications teleconference to ensure that we were up to date with the Department's plans, and that our language was consistent with other national organisations.

### ***Wales Transplantation Advisory Group (WTAG)***

49. The HTA attended a WTAG meeting in March. The key points and items raised at this meeting included:
- a. Updates on the DCD and DBD consent and referral rates in Wales
  - b. Future updates to the Welsh Code of Practice in relation to opt-out changes in England
  - c. Deemed consent in England
  - d. EU exit
  - e. Campaign work on public information regarding living organ donation
  - f. A refresh of the advisory group's future priorities.

### ***Living donation week and World Kidney Day***

50. The HTA worked with NHSBT to produce social media and website content for their campaign to highlight the importance of living organ donation in March. The campaign coincided with World Kidney Day on 14 March.
51. We promoted information on our role in regulating living organ donation and the important work IAs do. We complemented our content with HTA case approval statistics and shared these via the February public newsletter.

***Research and Anatomy compliance updates reports***

51. In March, we published a report summarising the findings from the 2017 round of compliance updates for the Research sector. The report was published via the March professional newsletter and it was made available on the HTA website.
52. The report reflects that Research sector compliance updates showed high levels of good practice. This data is consistent with our experiences of regulating the sector via our inspection protocols and supports our view of the sector as 'low risk'.
53. The compliance update report for the Anatomy sector has been drafted and will be published in quarter one 2019/20.

***Engagement with the public review panel***

54. Members will recall that the HTA have a public review panel that we occasionally contact to seek their feedback on our public guidance.
55. In quarter four, we sought feedback from the public panel on our Public Codes F and G. We received 40 responses in total and on average these guides were rated 4 out of 5 stars.

***Engagement with licensed establishments***

56. We published professional newsletters in January and March of quarter four (details below in the Digital Communications section). Further details on our work engaging with licensed establishments can be found in the 2018/19 Quarter Four Development Report.

## Delivery KPI narrative

### Performance against 2018/19 KPIs

57. KPI 3 (timely enquiry responses) is marked as green in quarter four, with 96% of enquiries being answered within 10 working days. This is a marked improvement from the last quarter where only 92% of enquiries were answered within 10 working days.
58. As agreed with the Authority, KPI 4 is not allocated a RAG rating. In January, eight out of nine major and critical shortfalls were completed on time. One remains open as further information was required from the establishment, which was delayed due to a change of DI. Despite follow up, the RM received evidence on 14 April 2019. In February, five out of eight major and critical shortfalls were completed on time. One was closed 81 days beyond the target as the lead inspector was awaiting confirmation from the DI of a final amendment to the CAPA plan. Another was closed 68 days beyond the target as the lead inspector no longer works at the HTA and the shortfalls were taken over by the support inspector (who asked the DI for further clarification on a number of points). The final one remains open pending installation and continuous monitoring of a new freezer (which is in the process of being ordered). In March, five out of 15 major and critical shortfalls were completed on time. Of the other 10, four submitted evidence late but this was assessed within the 28 day timeframe; one had evidence submitted before the final deadline date although our assessment took longer than 28 days; one submitted evidence 12 days late and this took a further month to assess as the lead inspector has left HTA and the support inspector needed to review; one remains open as we await confirmation that the US tissue bank has bought a piece of equipment; and a further three shortfalls remain open as these relate to the same company which is going into administration hence these shortfalls will not be addressed.
59. All other Delivery KPIs for quarter 4 are within target or tolerance and marked as **green**.

## Annex A – Statistics and background information

### Regulation

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

Type of site visit	Q4 2018/ 19	Q3 2018/ 19	Q2 2018/ 19	Q1 2018/ 19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Routine inspection	39	41	37	40	157	150	136
LAAV - new application	1	3	3	2	9	11	18
LAAV – variation	0	0	1	1	2	0	1
Satellite site inspection	11	16	8	14	49	66	46
CAPA follow up	1	1	3	1	6	5	1
Non-routine inspection	0	0	0	0	0	4	1
<b>Total sites visited</b>	<b>52</b>	<b>61</b>	<b>52</b>	<b>58</b>	<b>223</b>	<b>236</b>	<b>203</b>

Table Two: Closed HTARIs in the post-mortem sector

52. 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.

53. 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.

54. 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.

<b>HTARI Classification</b>	<b>Q4 2018 /19</b>	<b>Q3 2018 /19</b>	<b>Q2 2018 /19</b>	<b>Q1 2018 /19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
Accidental damage to a body	14	12	9	12	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	0	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	4	1	2	1	8	4	7
Disposal or retention of an organ against the express wishes of the family	1	0	0	0	1	5	0
Discovery of an organ or tissue following post-mortem examination and release of body	5	2	0	1	8	9	4
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	1	0	0	0	1	1	1
Loss of an organ	0	1	0	1	2	6	0
Major equipment failure	1	0	0	3	4	8	8

<b>HTARI Classification</b>	<b>Q4 2018 /19</b>	<b>Q3 2018 /19</b>	<b>Q2 2018 /19</b>	<b>Q1 2018 /19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent	0	0	1	1	2	2	1
Post-mortem examination of the wrong body	0	1	3	0	4	3	2
Release of the wrong body	0	4	2	4	10	15	9
Removal of tissue from a body without authorisation or consent	0	4	2	0	6	1	2
Serious security breach	0	5	3	2	10	8	1
Viewing of the wrong body	0	2	1	2	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	5	10	12	11	38	28	12
<b>Total</b>	<b>31</b>	<b>42</b>	<b>35</b>	<b>38</b>	<b>146</b>	<b>149</b>	<b>89</b>

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

55. 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.

	<b>Q4 2018 /19</b>	<b>Q3 2018 /19</b>	<b>Q2 2018 /19</b>	<b>Q1 2018 /19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
<b>Number of reported HTARIs</b>	64	35	47	59	205	230	160

Table Three: Closed SAEARs in the human application sector

56. 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.
57. 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.
58. 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	Q4 2018/19	Q3 2018/19	Q2 2018/19	Q1 2018/19	2018/19 Total Year	2017/18 Total Year	2016/17 Total Year
Event linked to Distribution	2	1	2	0	5	1	6
Event linked to End use	0	0	0	0	0	0	0
Event linked to Materials	0	0	0	0	0	1	2
Event linked to Preservation	0	0	0	0	0	0	4
Event linked to Processing	7	4	2	7	20	21	13
Event linked to Procurement	13	9	4	14	40	18	11
Event linked to Storage	2	1	0	1	4	10	10
Event linked to Testing	3	3	1	5	12	6	0
Event linked to Transportation	2	1	0	1	4	2	2
Event linked to Other process	2	1	0	2	5	8	4
<b>Total – Events</b>	<b>31</b>	<b>20</b>	<b>9</b>	<b>30</b>	<b>90</b>	<b>67</b>	<b>52</b>
Reaction in Donor	0	0	0	0	0	2	0
Reaction in Recipient	0	0	1	2	3	10	8
<b>Total – Reactions</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>12</b>	<b>8</b>
<b>Total – Events and Reactions</b>	<b>31</b>	<b>20</b>	<b>10</b>	<b>32</b>	<b>93</b>	<b>79</b>	<b>60</b>

Table Three B: Reported SAEARs in the human application sector

59. 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.

	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
<b>Number of reported SAEs</b>	67	65	63	84	279	157	83
<b>Number of reported SARs</b>	13	13	11	7	44	27	24
<b>Total</b>	<b>80</b>	<b>78</b>	<b>74</b>	<b>91</b>	<b>323</b>	<b>184</b>	<b>107</b>

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

60. During 2017/18, a total of 5040 organ transplants, from 1575 deceased and 993 living donors, were carried out in the UK. (England, Wales, Northern Ireland and Scotland).

61. 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.

62. 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.

<b>Type of Event or Reaction</b>	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
<b>Events</b>	9	6	3	2	20	29	28
<b>Reaction in Donor</b>	0	0	0	0	0	1	0
<b>Reaction in Recipient</b>	7	1	7	5	20	17	18
<b>Total</b>	<b>16</b>	<b>7</b>	<b>10</b>	<b>7</b>	<b>40</b>	<b>47</b>	<b>46</b>

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

63. 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.

	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
<b>Number of reported ODT SAEs</b>	12	13	2	6	33	22	38
<b>Number of reported ODT SARs</b>	8	10	2	9	29	15	26
<b>Total</b>	<b>20</b>	<b>23</b>	<b>4</b>	<b>15</b>	<b>62</b>	<b>37</b>	<b>64</b>

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

	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>2018/19 Total Year</b>	<b>2017/18 Total Year</b>	<b>2016/17 Total Year</b>
Approvals	24	17	17	13	71	22	38

Table Six: Living organ donation cases

	Type of case										Number of cases considered	TOTALS	
	Directed kidney		Directed altruistic kidney		Non-directed altruistic kidney	Paired or pooled kidney	Directed liver lobe		Non-directed altruistic liver lobe	Directed small bowel		Approvals by the Living Donation Assessment Team	Approvals by Authority panels
	LDAT	Panel	LDAT	Panel	Panel	Panel	LDAT	Panel	Panel	LDAT			
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
Q1 18/19	211	1	5	1	20	61	4	0	1	-	304	220	84
<b>18/19 Total Year</b>	<b>863</b>	<b>1</b>	<b>12</b>	<b>2</b>	<b>95</b>	<b>220</b>	<b>30</b>	<b>0</b>	<b>4</b>	<b>1</b>	<b>1228</b>	<b>906</b>	<b>322</b>
<b>17/18 Total Year</b>	<b>855</b>	<b>1</b>	<b>6</b>	<b>5</b>	<b>98</b>	<b>201</b>	<b>36</b>	<b>0</b>	<b>12</b>	<b>-</b>	<b>1214</b>	<b>897</b>	<b>317</b>
<b>16/17 Total Year</b>	<b>874</b>	<b>21</b>	<b>10</b>	<b>3</b>	<b>91</b>	<b>113</b>	<b>46</b>	<b>0</b>	<b>5</b>	<b>-</b>	<b>1163</b>	<b>930</b>	<b>233</b>

\* Q2 includes two cases considered using the 'emergency out of hours' process and one case in Q4 considered using the 'emergency out of hours' process.

## Communications

### Social media

60. In quarter 4, the HTA's Twitter account had 2,169 followers, up from 2,098 in the previous quarter. Our engagement rate stayed at 1.3 % during quarter four, with a peak rate of 5.4%.
61. On average, HTA tweets were seen by 700 people per day, decreased from 926 in quarter three.

### Table Seven:

Month	Impressions	Profile Visits
January	22.4K	Data not available
February	12.8K	88
March	27.9K	1372

62. Tweets with the highest reach and engagement in quarter four were about:
- Organ donation and transplantation  
Information about the multi faith roundtable event in February
  - Organ donation and transplantation  
About living kidney case approval stats for living donation week.
  - Post-mortem  
Promoting the eCPD app on strategic issues facing mortuary services.
  - Corporate  
Recruitment for the Digital Communications and Transplant Managers
  - Organ donation and transplantation  
Information on the January IA bulletin.
63. There are 870 Facebook 'likes' on the HTA page, up from 848 in quarter three. The HTA also had 635 followers for its LinkedIn company page, up from 606 in quarter three.

Digital communicationsTable eight: Digital users

	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>Q4 2017/18</b>	<b>2018/19 Year so far</b>	<b>2017/18 Total Year</b>
<b>Users</b>	87,437	78,090	70,938	69,168	69,818	218,196	237,457
<b>Page views</b>	336,543	288,025	271,911	263,278	300,228	823,214	949,008
<b>Pages viewed per session</b>	2.22	2.17	2.24	2.25	2.51	2.29	2.79
<b>Average session duration</b>	00:01:41	00:01:42	00:01:40	00:01:46	00:02:12	00:01:60	00:02:29
<b>Online enquiries</b>	323	358	334	284	355	1,029	1,146
<b>eNewsletter signups</b>	170	125	475	431	432	1031	1,552

64. The highest viewed pages are:

Table 9: Page views

<b>Highest viewed pages</b>	<b>Q4 2018/19</b>	<b>Q3 2018/19</b>	<b>Q2 2018/19</b>	<b>Q1 2018/19</b>	<b>Q4 2017/18</b>	<b>2017/18 Total Year<sup>1</sup></b>
Donating your body info	24,634	23,457	25,802	27,737	22,866	71,208
Medical school search	13,179	12,925	14,129	13,523	17,089	55,506
Codes of Practice and Standards	8,411	8117	6,572	7,605	8.664	33,017
Body donation FAQs	4,446	5633	6,562	6,415	10,281	34,503
Guidance for professionals	6,082	4899	4,338	4,694	5,746	22,115

65. The number of page views for our webpages on the Human Tissue Act and the establishment search page increased in quarter four.

<sup>1</sup> Data first collected in 2016/17

Newsletters

66. The HTA sent out a professional newsletter in January and March and an Independent Assessor bulletin in January. The HTA public newsletter was sent out in February.
67. The government average is for 24% of subscribers to open newsletters.

Table 10: Professional newsletter

<b>Month</b>	<b>Recipients</b>	<b>Open rate</b>
May 2018	4,327	34%
July 2018	4,380	34%
September 2018	4,469	28%
December 2018	5,795	31%
January 2019	4,564	47.8%
March 2019	4,837	31.5%

Table 11: Independent Assessor bulletin

<b>Month</b>	<b>Recipients</b>	<b>Open rate</b>
July 2017	272	26%
November 2017	272	35%
January 2018	268	44%
July 2018	266	36%
October 2018	265	37%
January 2019	265	37.5%

Table 12: Public newsletter

<b>Month</b>	<b>Recipients</b>	<b>Open rate</b>
October 2017	1,086	29%
December 2017	1,249	38%
February 2018	1,249	40%
June 2018	1,371	49%
August 2018	1,471	45%
December 2018	1,606	41%
February 2019	1,837	39%

Media coverage

68. During quarter 4, coverage which directly mentioned the HTA included:

a. **HTA Chair, Nicola Blackwood, appointed as Health Minister and elevated to the House of Lords**

- [Former MP put in the Lords and made a health minister \(HSJ\)](#)
- [Theresa May hands plum House of Lords job for life to Tory MP who lost her seat \(Mirror\)](#)
- [Defeated Oxford MP given peerage and ministerial post \(BBC News\)](#)

b. **The Royal Glamorgan Hospital's post mortem inspection findings**

There was widespread media coverage on issues identified at the Royal Glamorgan Hospital following an HTA's inspection in March 2018. All articles reference findings from the HTA report and feature quotes from HTA's Director of Regulatory Delivery, Nicolette Harrison.

- [Health board put under 'enhanced monitoring' after stillbirths and baby deaths \(Wales Online\)](#)
- [Cwm Taf Health Board apology over mortuary failings \(BBC\)](#)
- ['Discrepancies' in how health board stored remains of babies \(ITV\)](#)

c. **Scottish Minister's interest in an adverse effect from a double transplant which left two recipients with cancer from the donor's organs**

- [Minister vows to get answers over double transplant tragedy which left two patients with cancer from donor's organs \(Sunday Post\)](#)

d. **Post mortem sector shortfalls**

Following data released via an FOI request, several national news outlets ran stories on some of the details, including:

- [Morgue blunders scandal as wrong bodies released to grieving relatives \(Mirror\)](#)
- [Shameful morgue blunders see families handed the wrong or damaged bodies and staff 'disposing' of foetal remains without permission \(Daily Mail\)](#)

e. **Further coverage of Pharmacells and Precious Cells International following the organisations entering administration**

- [Frozen cells at risk after firm with laboratories in London and Glasgow fails \(The Times\)](#)

**Annex B – SAEARs / HTARI details****Human Application – Serious Adverse Events**

Case Number	Process Event Linked To	Description of Event
CAS-42679-N3W9	Transportation	Cryoshipper sustained a heavy impact during transit resulting in failure to record temperature of stem cells in transit. However temperature of stems cells was maintained and patient successfully engrafted.
CAS-41743-F9G0	Processing	Contamination detected following processing using a closed system. Pre-processing sample was clear. Sampling technique likely source of contamination and measures taken to address this
CAS-38634-H1K9	Transportation	Frozen stem cell unit dropped resulting in leakage into outer bag. Salvage protocol implemented.
CAS-45879-B4X4	Other (please specify)	Microbial contamination of stem cell unit reported by procurement centre. No deviation to collection procedure and subsequent testing was negative for contamination. Patient successfully engrafted.
CAS-45239-Q9G2	Processing	Contamination detected in post processing sample of tissue. Patient has engrafted
CAS-43694-W9D7	Storage	Loss of a unit of stem cells, during transfer to a new storage tank, due to ingress of liquid nitrogen. Risk assessment conducted and no other units affected.
CAS-44353-C7C1	Processing	Contamination of one out of two bags of stem cells collected. Contamination was attributed to poor harvesting techniques. Staff retrained in collection and sampling procedures.
CAS-43969-Z6Y8	Processing	Microbial contamination detected in backup unit of stem cells post-processing. Unit to be released under concession.

CAS-47670-G9K7	Testing	Donor samples for mandatory markers taken outside required timeframe. SOP amended to reflect testing timing requirements. Donor re-called for repeat testing.
CAS-43524-D1N1	Processing	Media used to for sterility testing did not perform as expected. All tissue and cells tested using the batch of media were re-tested or risk assessment undertaken and any affected tissue will be issued under concession.
CAS-46737-Q0D2	Processing	Human error led to incorrect procedure being used resulting in loss of sample. Re-training delivered to prevent risk of re-occurrence.
CAS-44489-V9P6	Procurement	Possibly donor derived contamination of stem cells. Decision taken, where possible, not to use Hickman line for apheresis procedures.
CAS-46260-N7H3	Storage	Recipient diagnosed with a condition which may affect sibling donor. Donated cells assessed and deemed that there is a low risk of transmission during storage. Cells to be issued without concessional release.
CAS-43345-F1D5	Distribution	Human error led to tissue being delivered that met exporting country's release criteria but not EU release criteria.
CAS-43343-V5Z5	Distribution	Human error led to tissue being delivered that met exporting country's release criteria but not EU release criteria.
CAS-47689-L0R4	Other (please specify)	Human error led to incorrect thawing of a frozen unit of cells. There was no effect on the cells and after infusion there was successful engraftment.

CAS-46753-Y0S0	Testing	Contamination of tissue was detected in post processing sample however, subsequent retesting was negative. Contamination may have been introduced during sampling of product. Staff retrained and requalified.
CAS-46755-S5G6	Testing	Contamination of stem cell unit reported to transplant centre via registry. Subsequent testing by transplant centre was negative. Likely source of contamination was during sampling by collection centre.
CAS-46878-F4K1	Procurement	Human error resulted in tissue being packaged for distribution inappropriately. Refresher training and procedures put in place to mitigate any reoccurrence of this error.
CAS-47511-C0B2	Processing	Inappropriate release of tissue outside of set criteria. Procedures and training have been put in place to try and prevent re-occurrence as well as the action to take if such an event occurs again.
CAS-46403-W6V7	Procurement	An unlicensed procurement was undertaken by another medical professional. Tissue has been stored and marked for release under concession. To prevent further re-occurrence the procedure for management of agreements has been updated.
CAS-44587-H3T4	Procurement	An unlicensed procurement was undertaken by another medical professional. Tissue has been stored and marked for release under concession. To prevent further re-occurrence the procedure for management of agreements has been updated.
CAS-44006-L0B5	Procurement	An unlicensed procurement was undertaken by another medical professional. Tissue has been stored and marked for release under concession. To prevent further re-occurrence the procedure for management of agreements has been updated.
CAS-44281-F3N9	Procurement	An unlicensed procurement was undertaken by another medical professional. Tissue has been stored and marked for release under concession. To prevent further re-occurrence the procedure for management of

		agreements has been updated.
CAS-46564-M4W3	Procurement	An unlicensed procurement was undertaken by another medical professional. Tissue has been stored and marked for release under concession. To prevent further re-occurrence the procedure for management of agreements has been updated.
CAS-47676-S2M8	Procurement	Positive test result for microbial contamination reported by collection centre. No contamination detected by transplant centre, cells used and patient engrafted.
CAS-41941-F9B0	Procurement	Tissue with incomplete serology test issued and transplanted. Subsequent test showed donor was negative for mandatory marker. Procedures and training have been put in in place to prevent reoccurrence of this incidence.
CAS-46765-D0H5	Procurement	Contamination of tissue during procurement most probably due to human error or sampling error.
CAS-46751-H8J4	Procurement	Human error, most probably, led to introduction of contamination during procurement. Recipient prescribed prophylaxis and successfully engrafted.
CAS-47965-J6M3	Procurement	Contamination detected in stem cell collection. Cause attributed to difficulty in cannulating the donor.
CAS-48231-D9M6	Procurement	Patient had pre-existing bacterial based infection consequently all autologous stem cells were contaminated with the same organism.

**Organ Donation and Transplantation – Serious Adverse Events**

Case Number	Incident Type	Brief description of incident
CAS-45061-S0Q3	ODT SAE	Findings post-transplant - post-mortem of donor indicated findings that could have had impact for recipients. No recipient impacted.
CAS-47353-D1H2	ODT SAE	Damage to organ - organ not transplanted
CAS-47744-J2C4	ODT SAE	Probable donor derived infection
CAS-47721-P3B3	ODT SAE	Probable donor derived infection
CAS-47743-M3K6	ODT SAE	Probable donor derived infection
CAS-47722-R9R2	ODT SAE	Probable donor derived infection
CAS-48083-B0S4	ODT SAE	Damage to organ - organ not transplanted
CAS-47656-N6D2	ODT SAE	Damage to organ - organ not transplanted
CAS-47680-T5G4	ODT SAE	Probable donor transmitted infection

**Organ Donation and Transplantation – Serious Adverse Reactions**

Case Number	Donor or Recipient	Incident type	Brief description of Reaction
CAS-47317-D6J8	Recipient	ODT SAR	Probable donor transmitted infection
CAS-46045-N2V7	Recipient	ODT SAR	Probable donor derived infection
CAS-47705-S8Y0	Recipient	ODT SAR	QUOD biopsy bleed at the site of the biopsy - recipient impacted
CAS-47267-C5Q8	Recipient	ODT SAR	QUOD biopsy resulted in damage to organ - recipient impacted
CAS-47322-Q8S1	Recipient	ODT SAR	Possible donor transmitted infection
CAS-48013-P4N6	Recipient	ODT SAR	QUOD biopsy - recipient impacted
CAS-47226-D9L2	Recipient	ODT SAR	Probable donor transmitted infection

**Post Mortem HTA Reportable Incidents**

Case Number	Incident Classification	Brief summary of HTARI
CAS-44804-J3F5	Discovery of an organ or tissue following post-mortem examination and release of body	Human and procedural errors led to discovery of tissue following release of a body.
CAS-46937-S1L2	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Delay in disposal of fetal remains.
CAS-45622-T7F3	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Retention of tissue resulting in a complaint
CAS-40018-G4P2	Accidental damage to a body	Human error lead to minor damage of a body while being transferred in to the mortuary
CAS-40899-Z4B6	Accidental damage to a body	Human error lead to minor damage of a body while being transferred in to the mortuary
CAS-40998-N3Z2	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Coroner asked for clarification on post mortem reports.
CAS-47165-F3M1	Discovery of an organ or tissue following post-mortem examination and release of body	Discovery of PM blocks and slides after release of a body.
CAS-46812-Z0S4	Inadvertent disposal or retention of an organ against the express wishes of the family	Due to human error, tissue was inadvertently disposed of.

CAS-45476-D4S4	Accidental damage to a body	Accidental damage to body.
CAS-47359-P0Y8	Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services	Due to a heating failure in the mortuary, PM cases were delayed.
CAS-45357-C9W0	Accidental damage to a body	Human error led to minor damage to a deceased person whilst being transferred into the mortuary.
CAS-44265-X8G7	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Insufficiently detailed SOPs led to temporary retention of tissue without appropriate consent.
CAS-42853-F7Z7	Accidental damage to a body	Procedural error led to minor damage to a deceased person whilst being transferred into the mortuary.
CAS-45985-Z2Y5	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Delay in sensitive disposal of pregnancy remains due to administration error
CAS-47078-L6Q0	Accidental damage to a body	Human error led to minor damage to a deceased person whilst being transferred into the mortuary.
CAS-47858-D1H7	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 inadvertent disposal of tissue.
CAS-42628-R3H1	Accidental damage to a body	Human error lead to accidental damage to a body

CAS-47579-Q6V6	Accidental damage to a body	Human error led to accidental damage to the deceased.
CAS-48084-P1M1	Accidental damage to a body	Human error led to accidental damage of the deceased
CAS-46729-W7R5	Discovery of an organ or tissue following post-mortem examination and release of body	Failure to follow procedure resulted in organ not being repatriated with a body before release.
CAS-46511-B0W5	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-48061-K8J2	Discovery of an organ or tissue following post-mortem examination and release of body	Due to human error, blocks and slides taken from PM were retained longer than necessary.
CAS-47480-Y6R4	Accidental damage to a body	Accidental damage to the deceased.
CAS-46504-J6G9	Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence	Discovery of PM tissue blocks and slides.
CAS-42225-H7N7	Major equipment failure	Major equipment failure resulted in deceased being transferred into back-up refrigerated storage.
CAS-45103-S1R3	Accidental damage to a body	Human error led to minor damaged to a deceased body when being transferred into the mortuary.
CAS-48567-B0T3	Accidental damage to a body	Human error led to minor accidental damage to a body during PM examination

CAS-46645-Y6C4	Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family	Disposal of tissue against wishes of family.
CAS-44536-Z9X3	Accidental damage to a body	Human error led to minor damage to a deceased person whilst being transferred out of the mortuary.
CAS-48752-R2B3	Accidental damage to a body	Accidental damage to the deceased when placing in the mortuary fridge.
CAS-46425-B6Q3	Discovery of an organ or tissue following post-mortem examination and release of body	Blocks and slides discovered in the mortuary after a release of the body.

## Authority Report

Development – Quarter 4 2018/19

<b>Date</b>	9 May 2019	<b>Paper Reference</b>	HTA (12/19)
<b>Agenda Item</b>	8	<b>Author</b>	Hazel Lofty
<b>Protective Marking</b>	OFFICIAL	<b>Author Contact</b> <a href="mailto:hazel.lofty@hta.gov.uk">hazel.lofty@hta.gov.uk</a>	
<b>Strategic objectives</b> (Development)	<ul style="list-style-type: none"> <li>• 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 our resources effectively;</li> <li>• Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;</li> <li>• 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;</li> <li>• Develop a blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.</li> </ul>		
<b>Relevant KPIs</b> (marked as red, amber, green, black or blue)	<ol style="list-style-type: none"> <li>1. <b>PROJECT: Assessment of Risk in the Human Application sector and update of processes to reflect this</b></li> <li>2. <b>PROJECT: Deliver a project to implement EU Directives on Coding and Import</b></li> <li>3. <b>PROGRAMME: Deliver a licensed establishment relationships programme as per plan specification</b></li> <li>4. <b>Develop our People and ICT Strategies as the first step in planning our organisational transformation programme</b></li> <li>5. <b>PROJECT: Develop a revised code of practice to provide practical guidance on the implementation of deemed consent for organ donation</b></li> </ol>		
<b>Related Strategic Risks</b> (marked as red, amber or green)	<ol style="list-style-type: none"> <li>1. <i>Failure to regulate appropriately (objectives a-d)</i></li> <li>2. <i>Failure to manage an incident (Delivery, Development and Deployment objectives)</i></li> <li>3. <i>Failure to manage expectations of regulation (objective c)</i></li> <li>4. <i>Failure to utilise our capabilities effectively (objectives a-d)</i></li> </ol> <p><b>(see paper 10a/19 for detailed information)</b></p>		

## **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 considered by the Senior Management Team (SMT) at its meeting on 25 April 2019.

## **Action required**

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

## **Director's summary**

5. As with quarter three, redeployment of resources to non-discretionary activity relating to the introduction of Deemed Consent in England, and preparations for the UK's exit from the European Union, has reduced the available resource for more discretionary development activity.
6. Work to implement the recommendations from the review of risk in the HA sector is now in train and will continue into 2019/20. Considerable work has also been undertaken to review and update website content and to launch the short online tests, which have been well received by stakeholders.
7. A number of pieces of work remain in the pipeline, and are planned for SMT discussion and business plan approval in quarter one 2019/20, along with more substantive scoping and planning for key development projects aligned to the HTA's organisational change programme.

## **Project updates**

### Core 2018/19 projects

8. The five projects below were considered core during 2018/19.

### EU Coding and Import Directives implementation

9. A small amount of residual work to finalise system and governance document changes remains outstanding. Prioritisation of resource into other business areas and the CRM

upgrade meant that this work was paused. This outstanding work is now in train and will be finalised and aligned with other development activities such as EU Exit, HA Risk and licence fees.

#### Licensed establishment relationship programme (LEEP)

10. Following an update to the Project Overview Document (POD), the group has worked as an internal advisory and steering group on engagement activities with licensed establishments. The group currently meets every three to four weeks and input has been sought on four major strands of stakeholder engagement activity:

i. *The remaining online tests on HTA legislation*

These were approved by Heads of Regulation and launched in the March professional e-newsletter, on the HTA website, and through social media. The online tests have been well received by stakeholders; a week following their launch we received over 350 responses, and this number continues to grow.

We will continue to monitor and promote these, and encourage our key stakeholders to share them through their networks. LEEP will also continue to discuss the data accumulated from these tests to support and inform other engagement activities.

ii. *Options for DI training*

The group have considered a number of options including online training, face-to-face workshops, or a combination of both, delivered by both the HTA and through partnering with other organisations, including external training providers. It has also considered what other resources could be made available for DIs through the HTA's digital channels.

Proposals will be presented to the senior management team in quarter one 2019/20, and discussed at the Stakeholder and Fees Group meeting in May.

iii. *Development of the HTA blog platform*

Members will recall plans for a blog that will be deployed through the HTA website. In quarter four, we tested the functionality and aesthetic of the blog platform with external members of the LEEP group.

We are currently reviewing this feedback with a view to launch the blog before the end of quarter one 2019/20. We also sought feedback on potential blog topics from the internal and external LEEP group, and via the March professional e-newsletter.

iv. *Licensing requirements*

LEEP also continues to scope and inform ongoing work to ensure that the HTA's licensing and associated compliance requirements are communicated clearly to stakeholders through a range of channels.

Assessment of risk in the human application sector

11. A project team has been established to begin delivery of the recommendations of the HA risk project. The team has developed a project plan to deliver agreed actions and has initially prioritised discrete pieces of work within the overarching project taking into account a number of live issues and work that will improve use of resources.
12. The project plan and proposed timelines have been reviewed and agreed by SMT.
13. Progress of the project will be reviewed by a Project Board consisting of the Director of Regulatory Delivery and the Head of Development. The Board will meet every six weeks.
14. Work to date has focused on improving the HTA's procedures and documentation relating to the oversight of licensable activities undertaken under the terms of third party agreements (TPAs). Systems have been put in place to strengthen oversight as part of routine inspection work and related governance documents updated accordingly. A thorough review of the information relating to TPAs on the HTA's website has been completed and necessary changes implemented. A dedicated webpage relating to TPAs has been created and will go live in quarter one 2019/20.
15. The steps taken to improve the HTA's TPA-related procedures were reviewed at a meeting of the Audit and Risk Assurance Committee in February.
16. Work is also underway to improve the systems and procedures relating to the review and authorisation of Preparation Process Dossiers and the HTA's inspection practices in the HA sector. Regarding the former, the focus is currently on the development of internal quality benchmarks for each tissue type as this will improve the consistency and efficiency of our review process. The HTA has also committed to undertake such work in support of the European Union GAPP (facilitating the Authorisation of Preparation Processes) project and outputs will be shared accordingly.

Introduction of the Organ Donation (Deemed Consent) Act 2019

17. The Organ Donation (Deemed Consent) Act 2019 received Royal Assent on 15 March 2019 and will now come in to force in England in April 2020.

18. The Bill places a duty on the HTA to provide practical guidance on deemed consent, which will be by the way of amended Codes of Practice.
19. More detailed information on progress with this work is provided in paper HTA (14/19) for discussion under item 12 of the agenda.

#### Organisational Transformation Programme

20. Further detail on the organisational transformation programme is provided in the Chief Executive's report.

#### **Additional 2018/19 projects**

21. In quarter four of 2018/19, the following projects were considered to be of importance.

#### EU Exit

22. In line with all DHSC delivery partners, the HTA was asked to implement 'no deal' plans in full throughout quarter four.
23. In quarter four resource was allocated to EU Exit preparedness to enable the HTA to respond to an increased number of information requests and stakeholder enquiries. Further planning work was undertaken to determine the extent of any licence variations and applications in event of a 'no-deal' scenario.
24. As well as internal preparedness, the HTA contributed to wider planning activities including participation in regular meetings with DHSC and its arms-length bodies. We issued advice for establishments on importing arrangements, operational preparedness and business contingency planning in our professional e-newsletters and separately in targeted communications to the HA and ODT sectors.

#### IA Sustainability Work

25. Work has continued on this project although with a lower priority in the absence of a Transplant Manager. A new Transplant Manager has now been appointed and will continue to scope and oversee delivery of the remaining parts of the project.
26. Work focussing on recruitment and IA reaccreditation has broadly been completed. Remaining work that will be prioritised this business year includes online training for IAs and the wider governance that supports the role at hospital level.

27. A paper detailing these work packages was discussed at the Transplantation Advisory Group on 8 May 2019.

#### Post-mortem sector development

28. The PM development work has progressed well, with the following areas nearing completion:

29. *Guidance for the standards*

The majority of the existing guidance for the standards has been reviewed and updated, (if required) based on inspection shortfall findings in 2017/18. All the updated guidance for the standards will be submitted to SMT for approval by the end of April 2019.

30. *PM sector publication*

Following a comprehensive review of the draft version of the publication in the early part of quarter four, the focus and the content of the publication has been refined to ensure that establishments within the sector can use the information (including themes that have been identified, advice and good practice) to identify activities that present increased risk and implement or strengthen practices to mitigate against them. The final draft is now being reviewed by the Communications Team in preparation for publication.

31. *Targeted advice and guidance*

A number of themes have been identified in the advice given to individual establishments in their inspection reports to improve compliance, demonstrating the need to provide certain pieces of advice and guidance to the sector in general. These themes are also closely linked to the shortfalls identified on inspection. Identifying areas that require sector wide advice and guidance will be an ongoing activity following the quarterly review of inspection and HTARI data.

#### Machine perfusion of organs for transplantation

32. As outlined in the quarter two development report, a targeted review was carried out on the use of machine perfusion of organs for transplantation in the ODT sector, which identified areas where the HTA could strengthen its regulatory oversight. Further work has been delayed due to redeployment of resources to other development projects.
33. Findings from the review pointed to limited oversight of machine perfusion by other regulators and a potential lack of clarity regarding regulatory boundaries.
34. The review has made a number of recommendations that will be considered by SMT in quarter one of 2019/20 for inclusion in the business plan. Areas identified to strengthen the HTA's regulatory approach are aligned with planned developments in the ODT

sector, including updating the Framework document and amending the Audit Assessment Criteria.

35. In addition to the above, recommendations also include collecting information on machine perfusion in compliance updates and establishing joint working practices to address providing clarity on borderline areas, regulation of novel technologies and horizon scanning. Strengthened working with other regulators will remain important for shared learning and regular cross-regulatory communication.

## Development KPI narrative

### Performance against 2018/19 KPIs

36. KPI 1 (HA Risk) and KPI 2 (EU Directives) are marked as **amber** for quarter four to reflect resourcing constraints which have limited progress.
37. All other Delivery KPIs for quarter four are within target or tolerance and marked as **green**.

### Projects scheduled to start in the next six months

Project	Brief description	Start date
Licensing and fees	A review of the framework under which we charge establishments for the regulation we undertake	Subject to approval in Q1
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 in Q1
Data and risk	Improved design of the HTA's risk-based approach to regulation through the better use of data	Subject to approval in Q1



## Authority Report

### Deployment – Quarter 4 2018/19

<b>Date</b>	9 May 2019	<b>Paper Reference</b>	HTA (13/19)
<b>Agenda Item</b>	9	<b>Author</b>	Richard Sydee
<b>Protective Marking</b>	OFFICIAL	<b>Author Contact</b> <a href="mailto:richard.sydee@hta.gov.uk">richard.sydee@hta.gov.uk</a>	
<b>Strategic objectives</b> (Deployment)	<ul style="list-style-type: none"> <li>a) Manage and develop our people in line with the HTA's People Strategy;</li> <li>b) Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money;</li> <li>c) Provide a suitable working environment and effective business technology, with due regard for data protection and information security;</li> <li>d) Plan and prioritise our resources to carefully balance activity across the organisation.</li> </ul>		

<p><b>Relevant KPIs</b> (marked as red, amber, green, black or blue)</p>	<p>11. Reduce attrition rates through improved selection and targeted retention measures to retain staff</p> <p>12. Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff</p> <p>13. Lead and advise on best recruitment procedures to maintain organisational capacity and capability</p> <p>14. Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to licence fee payers through limiting growth in licence fees</p> <p>15. Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to licence fee payers through limiting growth in licence fees</p>	<p>Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly)</p> <p>Percentage of Regulation Managers with more than one year of service (high risk if less than 80%) (reported quarterly) Consideration of Senior Inspector role (Q1)</p> <p>Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly)</p> <p>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)</p> <p>Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health Grant-in-Aid and devolved governments income) (reported quarterly); Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly)</p>
<p><b>Related Strategic Risks</b> (marked as red, amber or green)</p>	<p>2 Failure to manage an incident</p> <p>4 Failure to utilise our capabilities effectively</p> <p>5 Insufficient, or ineffective management of financial resources</p> <p><b>(see paper 10a/19 for detailed information)</b></p>	

## **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 considered by the Senior Management Team (SMT) at its meeting on 25 April 2019.

## **Action required**

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

## **Director's summary**

5. Recruitment and retention activity continues to take a lot of focus. Tight labour market conditions have presented a number of difficulties in filling roles. Two posts need to be filled at Head level including the Head of HR.
6. There was a considerable amount of time dedicated to high quality learning and development during quarter four enabled by additional funds. Good progress has been made on improving RM induction and a strategic decision has been taken to give two RMs additional training duties to support this on an ongoing basis. This is taking place instead of filling further senior RM roles.
7. SMT continues to engage staff on the organisational change due to take place in the coming two to three years.
8. The interim year end financial position, ahead of final accounting adjustments and audit sign off, is a surplus of £212k income against expenditure. This includes notional income received from DHSC of £178k to offset depreciation and amortisation costs. We anticipate this figure will move significantly as we finalise a number of adjustments in relation to the impairment of debtors and audit scrutiny.

## **People**

### People Strategy

9. The revised People Strategy was launched at an all staff meeting in March. As part of this, we undertook group exercises to engage staff in our proposed initiatives, to better

understand any concerns they may have and to engage staff on the issues they see as priorities. Overall feedback has been positive.

### Training

10. The additional funding available in quarter four allowed us to offer seven different group training courses. The courses were made available to all staff and covered the following topics: paediatric pathology, implementing policy, dealing with vulnerable people, writing effective written briefs and submissions, persuading and negotiating, root cause analysis and clean room training.
11. A further two group training courses were delivered for line managers covering recruitment interview skills and unconscious bias.
12. In addition to the group training courses, the additional funding allowed staff to attend 11 individual training courses to address development needs within their current roles. These courses covered topics such as: remote leadership, change management, developing social media strategy, public speaking, social media marketing, copywriting, agile project management and coaching and mentoring. As part of these courses, three staff have obtained practitioner level qualifications.

### Recruitment

13. We have advertised six vacancies in quarter four. Over the last twelve months, we have seen a reduction in the volume of applications received and this was particularly evident during quarter four.
14. The overall quality of applications for corporate roles (in terms of applicants meeting the person specification for roles) has also decreased and we are experiencing a greater number of applicants not responding to invitations for interview, not arriving for the interview on the day, or withdrawing due to having received other job offers prior to attending interview. In relation to regulatory vacancies, we have continued to attract sufficient numbers of high quality applicants and have continued to recruit successfully.
15. In most circumstances, interviews are scheduled to take place within approximately ten days of an advertisement closing, allowing for short listing to take place and one weeks' notice of interview. As such, we do not believe the length of our recruitment process is a significant contributor to this issue.
16. Having spoken with other organisations, both within the public and private sectors, we do not appear to be alone in this experience. Low unemployment and uncertainty relating to EU Exit are believed to be contributing factors.

17. We held an externally facilitated workshop in quarter four to explore and better understand feedback from seven Regulation Managers who had joined us between May 2018 – January 2019. Feedback is consistent with that we have received previously.
18. Work continues on the RM induction programme and we hope to be in a position to launch this early in the new financial year. Feedback from the most recent new starter, who has had access to the new induction material, suggests that it will address a number of the concerns that have been raised.
19. We have asked for expressions of interest internally in two Regulation Manager – Training roles. The key focus of these roles will be to support induction, training and continuous development of our Regulation Managers.
20. External consultants were contracted to complete an organisation-wide training needs analysis during January to March. We are still awaiting the final report and data, but initial feedback from staff indicates this was a positive experience. The data will be used to develop a structured and targeted learning and development plan for 2019-20.
21. As we move towards greater remote working, we will need to implement home workers contracts. At present, we only have one pay framework, as part of which London weighting is built into each pay band. As part of our move to home workers contracts, we will need to develop a second 'national' pay framework. The cost implications of this will likely require a business case to be submitted, however we cannot be certain of this until the 2019-20 Civil Service Pay Guidance is published in April/May. For this reason, we have revised the proposed implementation of home workers contracts to align with the office move in 2021.

## Finance

### Financial position for Q4 2018/19

22. At the end of the 2018/19 financial year, we are reporting a surplus against budget of **£212k. This is ahead of likely significant year end adjustments which may substantially reduce this interim figure.**
23. The table below shows the summarised financial position as at 31 March 2019, which is made up of an over recovery in our income of **£269k** and an over spend in revenue expenditure of **£57k**.

**Table One: Income and Expenditure summary – March 2019****Summary - Income & Expenditure****For the Twelve Months Ending 31 March 2019**

	Year to Date			
	Actuals	Budget	Variance	
	£	£	£	%
<b><u>INCOME &amp; EXPENDITURE SUMMARY</u></b>				
Income	(5,122,303)	(4,853,588)	(268,715)	5.54%
Less:				
Expenditure	4,893,647	4,836,835	56,812	1.17%
<b>Net (surplus)/deficit of income over expenditure</b>	<b>(228,656)</b>	<b>(16,753)</b>	<b>(211,903)</b>	

**INCOME**

24. We have exceeded our budgeted income by **£269k** largely due to additional income in the form of ring-fenced RDEL **£178k** from DHSC, from secondments **£54k**, increased income from Devolved Governments **£12k**. The balance of increased income coming from rent and associated costs.
25. Our licence fee income overall is in line with budget with a small over recovery of **£1k** after writing off bad debts of £30k. This is represented by under recoveries within Human Application, ODT and Post Mortem sectors, offset by over recoveries in Application fees, Anatomy, Public Display and Research sectors.
26. Table 2 below gives a full breakdown of income streams and their respective variances to budget.

**Table Two: Income Summary – March 2019****Income Summary****For the Twelve Months Ending 31 March 2019**

	Year to Date			
	Actuals £	Budget £	Variance £	%
<b>Grant In Aid</b>				
GIA	703,000	703,000	0	0.00%
Non Cash cover	178,600	0	178,600	0.00%
<b>Sub-Total</b>	<b>881,600</b>	<b>703,000</b>	<b>178,600</b>	<b>25.41%</b>
<b>Licence Fees</b>				
Application Fees	64,610	40,000	24,610	61.53%
Anatomy	93,000	93,760	(760)	-0.81%
Post Mortem	1,151,567	1,155,760	(4,193)	-0.36%
Public Display	20,175	18,950	1,225	6.46%
Research	639,820	630,150	9,670	1.53%
Human application	1,394,968	1,417,870	(22,902)	-1.62%
ODT	290,270	297,170	(6,900)	-2.32%
<b>Sub-Total</b>	<b>3,654,411</b>	<b>3,653,660</b>	<b>751</b>	<b>0.02%</b>
<b>Other</b>				
Other income (Rent)	363,809	340,533	23,276	6.84%
Other income (Secondees)	91,403	37,724	53,679	142.29%
Devolved Assemblies	131,081	118,671	12,410	10.46%
<b>Sub-Total</b>	<b>586,293</b>	<b>496,928</b>	<b>89,365</b>	<b>17.98%</b>
<b>Total Income</b>	<b>5,122,303</b>	<b>4,853,588</b>	<b>268,715</b>	<b>5.54%</b>

**EXPENDITURE**

27. Table three below shows that our total revenue expenditure is over budget by **£57k** with **£96k** underspend relating to staff salaries and wages and the balance of **£153k** over-spent on Non-staff costs.

28. We have carried a number of vacancies at Manager level over the year, which has impacted the underspend year in this area. In addition, a notional accrual for staff annual leave is £15k higher this year which may be due the late Easter break.

**Table Three: Summary Expenditure – March 2019****Summary - Expenditure****For the Twelve Months Ending 31 March 2019**

	Year to Date			
	Actuals	Budget	Variance	
	£	£	£	%
<b>EXPENDITURE SUMMARY</b>				
Staff Costs	2,901,295	2,997,457	(96,162)	-3.21%
Non Staff Costs	1,992,352	1,839,378	152,974	8.32%
<b>Total Expenditure</b>	<b>4,893,647</b>	<b>4,836,835</b>	<b>56,812</b>	<b>1.17%</b>

29. As a result of our improved income position, due to cover for depreciation and amortisation costs from DHSC, SMT took the decision to commit additional funds for key activity in the last quarter. This meant that we were able to commit additional spend which shows as an overspend against our original budget, the significant ones are detailed below:

- Within Training and Recruitment, we over spent by **£39k**. The majority of which relates to Corporate training for staff **£27k** and an overspend in our recruitment budget by **£12k** which reflects the recent successful recruitment rounds towards the end of the year.
- Within IT & Telecommunications we have overspent by **£65k** which relates to consultancy work around our CRM upgrade that cannot be charged to capital, consultancy support on developing our information governance policies and smaller items of hardware purchased that cannot be capitalised.
- Our legal and professional fees have exceeded budget **£33k** due to unbudgeted legal costs for a case that was settled in quarter three of this year **£38k** offset by underspend within Internal Audit costs **£5k**.
- Consultancy where we normally charge our staff survey costs are over budget by **£45k**. Spends relate to staff wellbeing survey, training needs analysis and professional advice on programme management.

- Against non-cash costs, we have written off **£30k** in unrecoverable debt where the establishment has gone into liquidation see *debtors*.

## Other key performance indicators

### Debtors

30. At 31 March 2019, our outstanding debts total **£271k** represented by 47 organisations.

31. Below is a breakdown by sector of the outstanding debts as at 31 March 2019.

### Outstanding Debtors by sector

Sector	Number of establishments	Value of debt £	%ge
NHS	29	£137,784.92	55%
Government Bodies	2	£84,486.42	34%
Non-Government Bodies	12	£27,448.30	11%
<b>Total</b>	<b>43</b>	<b>£ 249,719.64</b>	<b>100%</b>

32. Our outstanding debtors (£249k) are higher at this end of this financial year compared to the same period last year (£5k) due to staff on leave over Christmas and January.
33. At quarter three we reported that two organisations had gone into liquidation with a total outstanding balance of **£30k<sup>1</sup>**. These have been removed from these figures as they have been written off as unrecoverable.
34. From our September billing run, there are outstanding balances totalling **£113k** represented by 19 accounts. All bar two of these are NHS Foundation Trusts. These accounts have been and will continue to be pursued. The latest Agreement of Balance exercise has prompted many establishments to request copies with promises to pay.
35. The Government Bodies value is represented by monies due from DHSC £9k and NHS Resolution £76k for a seconded employee and rent respectively. Both were invoiced in March.

### Financial position for 2019/20

36. The start of the new financial year has seen additional expenditure pressure emerge due to announcements in February 2019 of an increase to the Employers contribution

<sup>1</sup> Precious Cells £16k and Pharma cells £14k

rate to the NHS Pensions Scheme (NHSPS). The contribution rate now stands at 20.68%, and increase of 6.5% points.

37. Unlike organisations funded vis NHS England the HTA has only received additional Grant in Aid (GIA) to cover 4% points of this increase, resulting in the remaining 2.5% points needing to be funded by HTA.
38. We calculate this cost to be £60k and have factored this in to HTA expenditure plans for the coming year. As this represents 1% of our overall budget this has inevitably led to some decisions to re-prioritise uncommitted expenditure.
39. Overall our expected income position for 2019/20, including all licence fees, GIA, income from devolved Governments and other sources, is forecast to be £5.26m and we have budgeted expenditure to meet this forecast.

## **Digital, data and technology and working environment**

### Business technology

40. At the beginning of this quarter we subscribed to a penetration testing and vulnerability assessment service enabling us to carry out continuous testing against our website, portal and internal infrastructure.
41. The first internal infrastructure assessment revealed a total of 292 vulnerabilities, of which 23 were rated high impact, and these have been fed into a continuous security improvement plan.
42. Seventeen vulnerabilities, including three high impact, were resolved by decommissioning a legacy server. Actions have been identified and are underway to address the remaining high impact vulnerabilities.
43. All of the remaining medium and low impact vulnerabilities will be prioritised according to the ease with which the vulnerability can be exploited and the impact on confidentiality, integrity and availability.
44. In this quarter we also completed and released the CRM system upgrade and are now running on the very latest on-premise version of the software.
45. We are now working to compile a comprehensive list of outstanding CRM change requests which will then be prioritised and costed (estimate) to form the basis of a CRM continuous improvement plan.

46. The additional income available in quarter four provided an opportunity to replace and refresh a number of pieces of IT equipment, with a focus on better aligning the office and remote working environments. We have replaced all monitors in the office with higher resolution, widescreen monitors and also issued monitors and docking stations to each member of staff working remotely for more than two days per week.
47. A number of desk assessments carried out in the previous year highlighted issues with laptop position and the use of telephone handsets. To pre-empt any discomfort felt by staff who have not been assessed we have also purchased laptop stands and telephone headsets.
48. We also purchased privacy filters for all staff to use with their Surface Book or Surface Pro in order to decrease the risk of 'shoulder surfing' when working on sensitive documents or emails.
49. During this quarter we have also replaced the office printers, reducing from three to two devices, and doubled the bandwidth of our office internet connection which provides an opportunity to dedicate a proportion of the bandwidth to voice and video traffic.

#### Information and Data

50. We engaged an information security consultancy to take forward further work on Information Governance and Assurance.
51. As a result of this work, the consultants have produced a draft Information Governance and Assurance Directive. The directive provides organisational, technological and legal context for information assurance and a supporting policy framework. It also defines terms of reference for key information governance roles and an information governance oversight group.
52. The consultants also provided detailed guidance on finalising a records management policy and a draft records retention schedule, and guidance on providing training and awareness for those staff working in information governance roles and staff more generally.

#### Working environment

53. The Department has formed a specific project stream to manage the proposed move of the HTA and other ALBs to the new Stratford location. The overarching project group has met twice and the HTA has nominated a number of staff members to attend sub group meetings relating to Information Technology, office environment and facilities management.

54. The overarching project is tasked to finalise the floor plan by end of May 2019 and provide data to inform formal business cases at organisation level. These are expected to be scrutinised and approved by each organisation by July 2019.
55. The building is expected to be ready for office fit out from late 2019 with initial occupation planned from October 2020

### **Deployment KPI narrative**

#### Performance against 2018/19 KPIs

56. KPI 11 Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) and KPI 12 Percentage of Regulation Managers with more than one year of service (high risk if less than 80%) were red at the end of quarter four with the attrition rate running at 20% in March and the percentage of Regulation Managers with more than a year of service running at 66%.
57. All other Deployment KPIs for quarter four are within target or tolerance and marked as **green**.

## Authority paper

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**Date** 9 May 2019 **Paper reference** HTA (14/19)  
**Agenda item** **Author** Ruth Joyce / Hazel Lofty

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## Introduction of Deemed Consent in England

### Purpose of paper

1. To provide the Authority with an update on progress with amendments to the HTA's Codes of Practice in preparation for the introduction of deemed consent in England, which is due to come into force in spring 2020.

### Decision-making to date

2. The Authority considered the proposed structure and initial draft of Code F - Donation of solid organs and tissue for transplantation at its meeting on 7 February 2019. This paper provides an update on progress to date.
3. The CEO approved this paper on 29 April 2019 for submission to the Authority.

### Action required

4. Members have been provided with an opportunity to comment on the working draft of Code F - Donation of solid organs and tissue for transplantation by correspondence in advance of this Authority meeting.
5. Members are asked to note the content of this paper and to provide feedback on issues of interpretation and substance in relation to the updates to Code F.
6. This paper has also been provided to members of the HTA's Transplantation Advisory Group (TAG) for discussion at its meeting on 8 May 2019.

## **Background**

### **Legislative update**

7. The Organ Donation (Deemed Consent) Bill 2017-2019 received Royal Assent on 15 March 2019. The Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) is due to come into force in spring 2020.
8. The Deemed Consent Act will only apply to 'permitted material'; DHSC are currently drafting regulations which specify the material which will not be covered by deemed consent. The regulations are expected to be similar to the approach taken in Wales and will be subject to formal consultation and Parliamentary approval. A consultation of the draft Regulations was published by DHSC on 29 April 2019, and closes on 22 July 2019.
9. The Deemed Consent Act places a duty on the HTA to provide practical guidance on deemed consent, which will be by way of amended Codes of Practice for professionals working in the sector. This will involve substantial amendments to the HTA's existing Code F - Donation of solid organs and tissue for transplantation.
10. In addition, minor amendments will be required to Code of Practice A - Guiding Principles and the Fundamental Principle of Consent, the common Annex which is part of all the Codes, and the Code of Practice on the Human Transplantation (Wales) Act 2013 to reflect the changes introduced by the Deemed Consent Act.

### **Key Amendments to Code of Practice F**

11. The current Code F provides guidance on both living and deceased donation. The revised Code will be split into two sections, published as separate documents, to cover living donation and deceased donation.
12. The first section, living organ donation, provides guidance to the clinicians working in living organ donation and HTA Independent Assessors (IAs). This section will not be affected by the introduction of deemed consent.
13. The second section, deceased organ and tissue donation, provides guidance to SNODs, Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. The Code will continue to provide practical guidance on 'appropriate consent' as defined by the HT Act in both England and Northern Ireland. Specifically, as required by the amended legislation, the Code will give guidance on the circumstances in which consent can be deemed.

### *The role of family, and faith and cultural considerations*

14. The role of family, and faith and cultural considerations, have been highlighted as key issues in the Parliamentary debates and Ministerial correspondence.
15. The HTA hosted a roundtable event in February with representatives of faith, secular, and cultural groups. The purpose of the event was to seek views on how conversations with a donor's relatives can be conducted in the most sensitive manner, taking both religious and cultural views and traditions into account.
16. The event had 24 external attendees, including representatives from several faith, secular, and cultural groups, and additionally colleagues from NHSBT, the Welsh NHS, and DHSC.
17. Additions have been made to Code F to reflect the role of the family in different donation situations. The Code has also been updated to reflect amendments made to the Organ Donor Register, including the recently introduced 'faith and beliefs declaration', and to make reference to appropriate faith and cultural support, where appropriate.

### *Other key areas*

The Authority's attention is drawn to the following areas for discussion:

18. The Deemed Consent Act sets out that (in circumstances where deemed consent applies) that the person is deemed to have consented '*unless a person who stood in a qualifying relationship...provides information that would lead a reasonable person to conclude that the person concerned would not have consented.*'
19. Consideration has been given to the situation where there is no recorded decision, and there are no family or friends in existence or available to provide information. The draft Code advises that in such circumstances there is no means of establishing the potential donor's decision and therefore donation cannot proceed.
20. This is in line with Parliamentary debates and assurances given by the Minister during the passage of the Bill.
21. The section of the Code on uncontrolled DCD has been adapted in light of feedback from stakeholders. As there is no active uncontrolled DCD programme in the UK, this guidance has been updated and included as an Annex to the main Code.
22. Deemed consent will not apply to specified types of relevant material as set out in paragraph 8 of this paper. The Code will need to be updated to reflect this once the regulations are made.

## **Project Update**

23. Updates on project progress and key milestones are provided to HTAMG and SMT on a monthly basis as a Development KPI on the HTA business plan. Progress is also discussed at monthly Deemed Consent project board meetings. The project board are responsible for sign off of key deliverables.
24. The project board membership includes the Head of Education and Professional Development (NHSBT) and the Head of Department, East Grinstead Eye Bank (non-NHSBT tissue bank), to ensure practitioner (user) views are reflected in preparation of the Codes.
25. Work is currently focused on drafting the amendments required to Code F. Initial feedback has been sought on a preliminary draft from our professional stakeholders which has been incorporated into the working draft.
26. Specialist advice on technicalities and clinical accuracy continues to be sought from professionals including Welsh Transplant colleagues, SN-ODs, NHSBT Organ Donor Register team, intensivists, and DHSC policy and legal colleagues.
27. Members will be given further opportunity to approve the draft Code and Consultation document prior to publication.
28. The project team are liaising closely with DHSC colleagues to ensure that the Code completes the Parliamentary approval process before the legislation comes into force. Timings post-consultation will largely be driven by the nature and volume of responses to the consultation.

## **Stakeholder Engagement**

29. In addition to the multi-faith roundtable, the HTA have also been participating in NHSBT's Organ Donation Campaign Advisory Group and Organ Donation Legislation Change meetings, to provide advice and guidance to NHSBT on their public awareness campaign for deemed consent which was launched on 25 April.
30. We continue to hold meetings and conversations with key stakeholders across the system and those who have an interest in this area have assisted in our engagement work.
31. A 12 week public consultation - aimed primarily at professionals - on Code F will be held over the summer, pending agreement of dates.

## **Next steps**

32. Feedback from Members will be combined with feedback from stakeholders to prepare the consultation version of the Code. Members will have the opportunity to approve both the consultation version of the Code and the consultation document. A teleconference can be convened if required.
33. Pending submission to the Minister, we anticipate opening the consultation in the first week of June.