# Eightieth Meeting of the Human Tissue Authority

**Date**  
27 June 2017

**Time**  
10:15 – 12:45

**Venue**  
Etc.venues  
One Drummond Gate, SW1V 2QQ

## Agenda

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| 10. | Understanding risk in the human application sector  
Discussion |
| 11. | Results of public evaluation  
Discussion |
| **Other Items** |   |
| 12. | Question and answer session |
| 13. | Any other business |

Meeting close  
Lunch: 12:45 – 13:30  
Conversations around death and dying: 13:30 – 16:30

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Minutes of the seventy-ninth meeting of the Human Tissue Authority

Date 4 May 2017
Venue Viceroy Suite, Grosvenor Hotel
      101 Buckingham Palace Road
      London, SW1W 0SJ

<table>
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<tr>
<th>Present</th>
<th>In attendance</th>
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<tr>
<td>Members</td>
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<tr>
<td>Sharmila Nebhrajani, OBE (Chair)</td>
<td>Allan Marriott-Smith (Chief Executive)</td>
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<tr>
<td>Dr. Hossam Abdalla</td>
<td>Sarah Bedwell (Director of Regulation)</td>
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<tr>
<td>Dr. Stuart Dollow</td>
<td>Vicky Marshment (Director of Policy, Strategy and Communications)</td>
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<tr>
<td>Amanda Gibbon</td>
<td>Richard Sydee (Director of Resources)</td>
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<td>Prof. Andrew (Andy) Hall</td>
<td>Hazel Lofty (Head of Regulatory Development)</td>
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<tr>
<td>William (Bill) Horne</td>
<td>Nicholas Baré (Head of Corporate Policy and Strategy)</td>
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<td>Glenn Houston</td>
<td>Caroline Browne (Head of Regulation – Post-Mortem)</td>
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<td>Prof. Penney Lewis</td>
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<td>Prof. Dame Sally Macintyre</td>
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<td>Bishop Graham Usher</td>
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<td>Dr. Lorna Williamson, OBE</td>
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<td>Prof. Anthony Warrens</td>
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<tr>
<th>Apologies</th>
<th>Observers</th>
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<tr>
<td>Jeremy Mean (Department of Health)</td>
<td>Rumku Basu-Owen (Department of Health)</td>
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<tr>
<td>Roger Wallis (Department of Health)</td>
<td>Lisa Carter (Regulation Manager)</td>
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**Item** | **Title** | **Action**
--- | --- | ---
**Welcome and apologies**
1. Sharmila Nebhrajani (the Chair) welcomed Members, attendees and observers to the seventy-ninth meeting of the Human Tissue Authority.
2. The Chair advised that Hazel Lofty (Head of Regulatory Development) was in attendance to present Item 11 – European Union Directives on Coding and Import Update [paper HTA (17/17)]. Caroline Browne (Head of Regulation) was also in attendance. Lisa Carter (Regulation Manager) from the HTA, would observe the meeting.
3. The Chair noted that this was the first time that Rumku Basu-Owen would attend the meeting from the Department of Health.
4. No apologies were received from Authority Members. The Chair noted that Anthony Warrens would only attend part of the meeting (Items 4 to 8).
5. Jeremy Mean and Roger Wallis (Department of Health) sent apologies.
6. The Chair advised Members that the Chief Executive would speak during Item 10 – White space for non-agenda items, on the developing proposal for the Authority’s strategy session in October. This agenda item would also provide Members with an opportunity to raise points that were important to them.
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**Item 2 Declarations of interest – Oral**
7. 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
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**Item 3 Minutes of 9 February 2017 – HTA (12/17)**
8. Ahead of the 4 May 2017 meeting, Members were asked to provide comments on the minutes for the Authority meeting on 9 February 2017, as well as for the minutes from the confidential session on cryopreservation.
9. Comments were provided by Amanda Gibbon, Bill Horne, Glenn Houston and Stuart Dollow.

10. In addition, it was noted that on page 7, paragraph 33 of the Authority minutes, the word “at” was missing from the sentence, “it was suggested that Authority Members could identify priority areas for future internal audit “at” its October strategy awayday”.

11. With the exception of these incorporated updates, the minutes were accepted as an accurate record of the meeting and of the confidential session.

### Item 4     Matters arising from 9 February 2017 – Oral

12. The Chair noted that all actions from the 9 February 2017 meeting were resolved, ongoing in nature or would be addressed by the senior management team during the meeting.

13. The Chair thanked Members for preparing for and attending their 2016/17 performance appraisals and noted that she would be attending her own performance appraisal on 8 May, with Clara Swinson at the Department of Health. The Chair noted that following her appraisal, she would begin to set objectives for Members for the 2017/18 year.

14. The Chair invited Bill Horne to update the Authority on the meeting of the Stakeholder Group on 3 May 2017. Bill Horne provided Members with an update on items discussed, which included: the current status of the Coding and Import Directives; the implementation of the HTA’s updated Codes and Standards; the outcome of the triennial review; joint inspections with the Medicines and Healthcare products Regulatory Agency (MHRA); and changes to the HTA’s representation process.

15. Bill Horne noted that a review would be carried out over the summer on the HTA’s three advisory groups (Stakeholder Group, Histopathology Working Group, Transplantation Advisory Group) to assess how they operate. This review aims to identify operational best practice and any standardised processes that could improve how they deliver
their respective remits. This will build on surveys undertaken by two of the groups, with a view to implementing any changes by the time the groups next meet in quarter three. This review will also consider whether these are the right groups to convene and whether the groups have the right membership.

16. The Chair asked Members for any other matters arising.

17. Members discussed an organ donation panel case where a donor had requested for his/her donated organ to be re-implanted if the organ could not be transplanted into a certain recipient. In the case, the donor was told that this was unlikely to be possible. Members raised the question as to why this was likely to be the case and, if so, whether more donors should be advised of this as it may affect consent. Members considered that there were circumstances in which it may not be possible to re-implant the organ; this would include the distance between the donor and the recipient and medical reasons. Sarah Bedwell agreed to seek advice and information about practice with NHS Blood and Transplant (NHSBT), and the British Transplantation Society.

Action One: Provide an update to the Authority’s 14 September 2017 meeting on any proposed changes to the HTA’s stakeholder and sector groups.

Action Two: Provide an update on the issue of consent and the reimplantation of organs ahead of the June 2017 Authority meeting.

Item 5  Chair’s Report – Oral

18. The Chair highlighted meetings of note that she had attended since 9 February 2017.

19. On 27 February 2017, the Chair and Chief Executive met with Lord O'Shaughnessy, following his appointment as Under Secretary for Health in December 2016. At the meeting, the remit of the HTA was discussed, with a particular focus on the risk posed by winter mortuary capacity. Given the upcoming General Election, there is the possibility of further Ministerial changes at the Department of Health.
20. On 24 March, the Chair and other Members took part in the second panel teleconference on organ donation, which is addressed in the Chief Executive’s report. The next meeting is scheduled for 30 May 2017.

21. In late March, the Chair signed-off the year-two update of the Authority’s three-year strategy. This was published alongside the 2017/18 Business Plan, on 3 April 2017. The Chair thanked Members who provided comments on a draft of the strategy, which was circulated following the 9 February 2017 Authority meeting.

22. On 3 April 2017, the Chair and other Members joined HTA colleagues to hear from Professor Barry Fuller (University College London) on the history and science of cryopreservation. The Chair noted that the discussion was very useful and that similar meetings on ethical issues should be held.

23. The Chair confirmed that Authority meeting dates for 2018 were in the process of being confirmed. The Chair asked Members to note confirmed meeting dates of:

   a. 8 February 2018;
   b. 10 May 2018; and
   c. 8 November 2018.

24. Dates for summer meetings in 2018, as well as dates for the Audit and Risk Assurance Committee (ARAC) meetings will be confirmed over the coming quarter.

25. The Chair confirmed that planning for the 27 June 2017 summer public event were well advanced. The title is, “conversations around death and dying”. The HTA has confirmed a broad range of speakers, and has received interest from over 200 attendees.
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<td>26.</td>
<td>Allan Marriott-Smith presented this item and introduced the report.</td>
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<td>27.</td>
<td>The Chief Executive reported that during quarter four, the senior management team reviewed and updated the strategic risk register, to reflect the delivery of the year-two update to the HTA’s strategy. One material change was to risk five – <em>insufficient financial resources</em> – which was expanded to become – <em>insufficient, or poor management of financial resources</em>. Allan Marriott-Smith reported that this change was made to allow him as Accounting Officer to assess the risks relating to the HTA’s expenditure plan, in addition to risks relating to there being sufficient funds in the budget to deliver the 2017/18 Business Plan.</td>
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<tr>
<td>28.</td>
<td>The strategic risk register will be reviewed at the 18 May 2017 Audit and Risk Assurance Committee (ARAC) meeting.</td>
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<td>29.</td>
<td>Allan Marriott-Smith confirmed that following the Authority’s confidential session on cryopreservation at its 9 February 2017 meeting, he had written to the Department of Health to outline the position agreed by the Authority. Draft papers will be finalised by the end of quarter one, which are being developed with input from other affected government agencies.</td>
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<td>30.</td>
<td>Allan Marriott-Smith reported that the HTA undertook a simulated test of its Critical Incident Response Plan on 9 March 2017. This test was observed by the HTA’s Internal Auditors, who will report their assessment of the test to the 18 May 2017 ARAC meeting. Amanda Gibbon, Chair of the Committee, noted that she would provide an update to Members at their 27 June 2017 Authority meeting.</td>
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<td>31.</td>
<td>Following questions from Members, Hazel Lofty confirmed that the Growth Duty, which came into effect on 29 March 2017, would affect the HTA in two ways. Firstly, the HTA will need to have regard to the desirability of promoting economic growth when developing policy and making regulatory decisions. Hazel Lofty confirmed that standard operating procedures and reporting templates have been updated to reflect the Growth Duty’s requirements. HTA colleagues are</td>
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aware of these changes. Secondly, the HTA will need to be prepared for future reporting obligations, though these will not take effect until a public consultation has been carried out, and secondary legislation has been enacted.

32. The Chair noted the importance of Members observing inspections of establishments. As noted in the Chief Executive’s Report, it has been challenging in some instances to arrange such observations. The Chair requested that Members be flexible in their approach to offers, as HTA colleagues must primarily consider the needs of establishments when developing the wider inspection programme. Sarah Bedwell agreed that HTA colleagues would be in contact with Members to propose potential inspection observations.

33. The Authority noted the content of this report.

**Action Three:** Report the findings of the Internal Auditor’s assessment of the HTA’s simulated test of its Critical Incident Response Plan, at the Authority’s 27 June 2017 public meeting.

**Action Four:** Provide Members with the strategic risk register that will be reviewed at the 18 May 2017 ARAC meeting.

**Action Five:** Arrange for Members to receive a list of upcoming inspections that may be suitable for Members to attend.

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**Item 7  Delivery Report – Quarter Four (year-end) HTA (14/17)**

34. Sarah Bedwell presented this item and introduced the report.

35. Sarah Bedwell reported that HTA data shows that there has been a rise in reportable incidents across the post-mortem, human application and organ donation and transplantation sectors between 2015/16 and 2016/17. However, current data from the post-mortem and human application sectors suggests that data has returned to 2014/15 levels of reportable incidents, which suggests that 2015/16 numbers were lower than normal. Data in the organ donation and transplantation sector shows a sustained rising trend.
36. Sarah Bedwell noted that this rising trend in the organ donation and transplantation sector is consistent with reporting trends in other regulated sectors, where a culture of reporting has developed after the implementation of a reporting requirement. NHSBT’s records show that the number of incidents reported in the sector has risen but that this appears to be a result of better reporting and of increased activity within the sector; a view supported by some Authority Members. The HTA will continue to monitor and discuss data trends with NHSBT.

37. Members supported this approach, and asked that a longer-term series of annual data be provided in future reporting, against the same denominator figures that NHSBT reports to the public.

38. Sarah Bedwell reported that during quarter four, the HTA made two referrals to the Police.

39. The first referral was made in December, following receipt of an intelligence report from the National Crime Agency. The HTA did not have any powers to investigate this case, but did refer it to the relevant local Police force for investigation. No action was taken because no crime appeared to have been committed in the UK.

40. The second referral related to an organ-matching website. Sarah Bedwell will keep members up to date with progress.

41. Vicky Marshment noted that following the Authority’s request, a new key performance indicator (KPI) would be measured in 2017/18, to ensure human tissue is used safely. In developing the indicator for this new KPI, the HTA will consider how safety is measured at comparable regulators, with a view to developing a series of measures that would be reported on annually.

42. The Authority noted the content of this report.

**Action Six:** Include longer-term series data for Serious Adverse Events or Adverse Reactions (SAEARS) and HTA Reportable Incidents (HTARIs) in reporting annually.
**Action Seven: Provide Members with an update on the Police referral relating to reward for organ donation when more is known.**

**Item 8  Development Report – Quarter Four (year-end) – HTA (15/17)**

43. Vicky Marshment presented this item and introduced the report.

44. Vicky Marshment reported that the project to implement the HTA’s updated Codes and Standards was in its final stages, following the Codes’ publication on 3 April 2017. The HTA’s Regulatory Managers had been well supported to start using the Standards to inspect licensed establishments, and establishments are prepared to be assessed against the new Standards, following a multi-channel programme of communications from the HTA.

45. As part of the communications programme, the HTA recorded and published webinars on each of the Codes on a dedicated YouTube.com page. This channel has proven to be an excellent way to communicate cost-effectively with establishments and other stakeholders. The HTA will record and publish webinars for the Coding and Import Directives, once they have been transposed into UK law.

46. Vicky Marshment reported that were two final milestones to complete for the project to be considered closed. The first was to publish a set of guides to the Codes and Standards for the public. The second was to carry-out a project implementation review to assess:

a. how the project was carried out;
b. feedback from Regulatory Managers on using the Standards; and
c. feedback from licensed establishments on the Standards with regard to inspections.

47. This review will be reported to the HTA’s Stakeholder Group at its October 2017 meeting and at the November 2017 Authority meeting.

48. Vicky Marshment reported that Annex A of the Development Report outlined the HTA’s proposed licensed establishment
49. The first elements of the programme are the publication of a web-based training resource and the creation of an online forum; both for designated individuals. The training package will be presented to Members at the 14 September 2017 Authority meeting. Vicky Marshment welcomed input from Members on the programme outline and invited interested Members to join the programme board.

50. Vicky Marshment reported that Annex B of the Development Report outlined the indicative timetable for the HTA’s licensing and inspection review. Given delays to the transposition and implementation of the Coding and Import Directives, resource was now available to dedicate to this review.

51. The review includes an assessment of risk in the human application sector. The HTA intends to update its processes to reflect the findings of the assessment. This assessment is a Development KPI in the 2017/18 Business Plan. The review’s results will be presented at the Authority’s strategy session on 19 October 2017.

52. The Authority noted the content of this report.

**Action Eight:** Present the findings of the project implementation review for the Codes and Standards project at the Authority’s meeting on 9 November 2017.

**Action Nine:** Present the online training package for the licensed establishment programme at the Authority’s meeting on 14 September 2017.

**Action 10:** Present changes to the HTA’s processes for inspections in the human application sector at the Authority’s strategy session on 19 October 2017.
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<td>53.</td>
<td>Allan Marriott-Smith presented this item and introduced the report, with assistance from Richard Sydee.</td>
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<td>54.</td>
<td>The Chief Executive noted that the recruitment process to replace the Head of Business Technology continued. Following an unsuccessful first round of interviews, further interviews will take place in early May. Measures to mitigate continuity risks have been put in place with our technology contractors, BCC and Webcurl.</td>
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<td>55.</td>
<td>The Chief Executive reported that the HTA’s Management Group reviewed its terms of reference during the quarter, and agreed to alter the standing items on the group’s meeting agenda, to focus on: providing assurance for agreed projects and activities; continuous business planning; and developing the group as a collective. The group will also focus on strengthening its formal planning processes in quarter one.</td>
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<td>56.</td>
<td>The Chief Executive reported that the HTA’s wiki became the internal homepage during the quarter. The wiki provides a user-content driven platform for colleagues to share information and intelligence, which is not appropriate to store on the customer relationship management (CRM) or quality management systems. Allan Marriott-Smith agreed to update the Authority with the wiki’s implementation at its 8 February 2018 meeting.</td>
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<td>57.</td>
<td>The Chief Executive reported the financial end-of-year position for the HTA. A gross surplus of income over expenditure was made (£44.7k), against a small budgeted deficit (£8.9k), which resulted in a net surplus of income over expenditure of £53.6k.</td>
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<td>58.</td>
<td>Richard Sydee reported that during the quarter, there was no improvement to the HTA’s debtors balance. Letters were dispatched to respective NHS Trusts and would be followed up by calls from the Director before other courses of action are considered.</td>
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<td>59.</td>
<td>External Auditors will present the HTA’s 2016/17 annual report and accounts to the 18 May 2017 ARAC meeting. The only outstanding issue is whether value added tax on rent for HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.</td>
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accommodation at Buckingham Palace Road should be treated as a contingent liability. The HTA’s position is that this is not a material issue.

60. The Authority noted the content of this report.

**Action 11: Update the Authority on the implementation of the HTA’s wiki at its 8 February 2018 meeting.**

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**Item 10** Item 10 White space for non-agenda items – Oral

61. The Chief Executive set out plans for the Authority’s strategy session in October. The session will focus on two strategic questions:

   a. does the HTA strategy, especially its regulatory model, provide optimum protection for public and professional confidence; and
   b. how does the HTA need to change by 2021?

62. Since the last review of the strategy, Members have been given a number of resources to help them form a view on these questions. These have included sector-based sessions on living organ donation and transplantation, human application and post-mortem. ARAC Members have also taken part in a risk-based review of the HTA’s regulatory model.

63. Further resources will be provided for Members, including a presentation on the research sector, to be given at the 14 September 2017 Authority meeting. The HTA will also share feedback from the regulated community and stakeholders gathered at the 27 June 2017 public event, and from colleagues at all-staff sessions throughout the summer.

64. The Authority noted the Chief Executive’s plans.

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**Item 11** European Union Directives on Coding Update – HTA (17/17)

65. Hazel Lofty presented this item and introduced the paper.

66. Hazel Lofty reported that the paper received by the Authority was drafted before the General Election was called. As a result, the Human Tissue Amendment Regulations 2017 now cannot be transposed and implemented before the summer.
recess. It is unlikely that they will come before the Houses of Parliament before the autumn.

67. Following the General Election, the new Government will need to take a decision as to whether it will implement the Regulations, before a Parliamentary timetable can be determined.

68. Rumku Basu-Owen noted that the Department intends to recommend the Regulations to the new Minister as a priority.

69. Hazel Lofty reported that the Department of Health’s consultation on the Directives, whilst short, generated thirteen high quality responses, across a broad range of sectors. During the consultation period, the HTA provided affected establishments with advice and guidance on the new regulatory requirements through two webinars.

70. The HTA is now well placed to implement changes to the existing regulatory framework. Delays to the implementation timetable mean that resources are being reallocated to other HTA projects and activities.

71. The Authority noted the content of this paper.

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<th>Item 12</th>
<th>Authority Standing Orders Update – HTA (18/17)</th>
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<tr>
<td>72.</td>
<td>Nicholas Baré presented this item and introduced proposed updates to the Authority’s Standing Orders. These included four material changes and other minor changes.</td>
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<td>73.</td>
<td>With more than two-thirds of Authority Members present, Members agreed to the following changes to the Authority’s Standing Orders.</td>
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a. **Standing Order 21**: Members agreed to amend the Standing Order to, “At any meeting of the Authority or its Committees, the Chair, if present, shall preside. If the Chair is absent, the Members present shall choose one of their number to preside. The Chair shall nominate a Member to preside in his/her place”.

b. **Standing Order 22**: Members agreed to amend the Standing Order to, “If the Chair is absent temporarily on
the grounds of a declared conflict of interest, the remaining Members shall choose one of their number to preside. The Chair will nominate a Member to preside in his/her place”.

c. Standing Order 29: Members agreed to remove the Standing Order in its entirety, as it was no longer relevant.

d. Annex 1: Scheme of delegation of powers to the Chief Executive, Officers and Committees: To reflect changes to the HTA’s Representation arrangements, which were agreed at the Authority’s 8 February 2017 meeting, Members agreed to the proposed changes, detailed in the paper.

e. Minor changes: Members agreed to other minor formatting and contextual amendments proposed in the paper.

Action 12: Update and publish the Authority’s Standing Orders.

Item 13 Any Other Business – Oral

74. The Chair asked Members to raise any other business.

75. In light of recent media coverage of Syrian refugees selling organs, Members discussed how the HTA monitors international organ trafficking through the World Health Organisation intelligence.

76. Allan Marriott-Smith agreed to discuss this with his counterpart at NHSBT at their next meeting.

77. No further business was raised.

Action 13: Discuss international organ trafficking with NHS BT and report back to the next possible Authority meeting.

The meeting closed at 16:41.
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 over the period since the quarter four, 4 May 2017 Authority meeting, that are not reported elsewhere.

2. This report is a standing item for HTA Authority meetings. At its quarterly meetings, the Authority usually receives three other standing items, which report on progress against delivering objectives set out in the HTA’s strategy. These items report on the HTA’s:
   
   a. Delivery – How we achieve our strategic objectives today;
   b. Development – How we will improve in the future; and
   c. Deployment – How we effectively use our people and resources.

3. Full reporting for quarter one will not be available for the June public meeting, so this report identifies key issues under each of the strategic themes.

4. Quarterly progress against the HTA’s key performance indicators can be found in papers published on the [HTA’s website].

Decision-making to date

5. No significant decisions have been made with respect to this report. The Senior Management Team (SMT) approved this report for submission to the Authority at its meeting on 15 June 2017.
Action required

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

Overview of strategic risks

7. In reviewing strategic risks for June, SMT concluded that the residual likelihood of risk one - *Failure to regulate appropriately* - has now been reduced to the extent that the risk rating could be downgraded to green. This is because the HTA now has an almost full complement of staff, with appointments (or cover arrangements) in place for all key posts, and an increasingly experienced cadre of Regulation Managers and other staff who are familiar with key governance arrangements.

8. SMT has reviewed the way in which risk five is described and propose the formulation - *Insufficient, or ineffective management of, financial resources*. This reflects both the risk of raising insufficient finance to fund the HTA in 2017/18 and beyond, and also the risks that our financial controls are inadequate, or we make poor decisions about allocating finances. The budget position for 2017/18 remains tight (with the residual risk rated yellow) but our assessment is that this is currently reducing.

Delivery

Organ trafficking

9. At its meeting on 4 May 2017, following media reports of Syrian refugees selling organs, the Authority expressed an interest to understand the full picture of how organ trafficking is deterred and monitored in the United Kingdom.

10. The Human Tissue Act 2004 makes the trafficking of organs illegal in this country. There are systems in place to regulate organ donation across the United Kingdom, which are designed to prevent trafficking.

11. In terms of living donation, there are many checks in the system as a whole to prevent paid organ donation taking place. The HTA has a regulatory role in making the final check to ensure that each donor is not being paid or coerced into the donation. The HTA must be satisfied on these points before a living donation can be approved.

12. This is undertaken via the Independent Assessment process. The HTA’s Guidance document to transplant teams and Independent Assessors has a section on prevention of trafficking - both of human beings and of organs. This sets out what trafficking means and provides key indicators to be aware of during contact with donors and patients.
13. In relation to organ donation from the deceased, all donations are managed through NHS Blood and Transplant (NHSBT), who allocate organs to patients on the national waiting list. Specialist Nurses for Organ Donation (SNODs) are involved in the majority of cases and a consent discussion is always held with the family.

14. In 2008, the United Kingdom signed the Declaration of Istanbul. The Declaration addresses the issues of transplant tourism, trafficking and commercialism and provides ethical guidelines for practice in organ donation on an international scale; however, it is not legally binding.

15. In addition, the United Kingdom has ratified the Council of Europe Convention on Action against Trafficking in Human Beings, which entered into force on 1 April 2009, and has also signed the Council of Europe Convention against Trafficking in Human Organs. This is the first international legally binding document to address the issue of organ trafficking from a criminal law point of view.

16. We have established links with the National Crime Agency which has shared intelligence with the HTA on the few occasions where organ trafficking may be indicated.

17. The more difficult aspect to monitor is the number of British patients seeking an organ transplant overseas, which is outside the HTA’s remit. To better manage and monitor this, discussions are taking place with other regulatory agencies. It is also important to recognise that not all of those patients travelling overseas for a transplant will be doing so illegally; many do so legitimately to receive an organ from a family member or friend, for example.

18. Members may be interested to note that Pope Francis has made the prevention of organ trafficking and transplant tourism a key aim of his pontificate, calling organ trafficking and human trafficking for the purpose of organ removal, “true crimes against humanity that need to be recognised as such by all religious, political and social leaders, and by national and international legislation”.

19. A world summit was held on the issue earlier this year, which resulted in a statement and several recommendations. Sally Johnson, Director of Organ Donation and Transplantation at NHSBT, attended and signed the statement on behalf of the United Kingdom. The HTA is working with NHSBT to help ensure that the recommendations of the summit are implemented.
Human forensic taphonomy

20. A team from the School of Applied Science at Huddersfield University continues to develop a proposal to create a human forensic taphonomy facility and is expected to share this with the HTA by the end of June.

21. Forensic taphonomy is the study of the post-mortem changes of human remains, focusing largely on environmental effects, including, decomposition of bodies in soil and water, and interaction with plants, insects and other animals. Currently, taphonomy facilities are only in operation in the United States of America and Australia.

22. In early April 2017, Caroline Browne and Chris Birkett met with colleagues from the Forensic Pathology Unit of the Home Office, to assist them in developing a recommendations paper for the Authority and the Department of Health to consider. This will set out the risks associated of enabling the facility to open without any form of regulatory oversight, as well as possible options for bringing the activity of human taphonomy within the scope of the HTA’s regulatory remit.

Cryopreservation

23. At its 9 February 2017 meeting, the Authority considered a paper relating to the issues raised by the recent case of a 14 year-old girl, who expressed a desire to be cryopreserved after her death; a process that is not covered by any of the scheduled purposes in the Human Tissue Act 2004. For the HTA, this case raises questions of dignity for the deceased and safety for health professionals.

24. As cryopreservation is an issue that is multi-agency in its effects, the Authority has asked HTA colleagues to work with the Department of Health and others to consider what guidance could be made available:

   a. to the public, which maps to the HTA’s core principles detailed in Code A; and
   b. for those who may be asked to facilitate the cryopreservation process as part of their job, for example, those working in licensed establishments.

25. Drafts of this guidance will be developed over the summer.

Freedom of Information Act (FOIA) 2000 requests

26. Since the Authority’s last meeting on 4 May 2017, the HTA received six FOIA requests. The requests were:

   a. Request one sought a list of post mortem sector establishments and designated individuals licensed in 2013/14.
b. Request two sought information on bespoke software systems used by the HTA as well as any consideration of the procurement of bespoke or off-the-shelf commercially branded software, which may need bespoke development.

c. Request three sought information on any cyber-attacks that had been carried-out on the HTA.

d. Request four sought the names of colleagues who carry out particular functions at the HTA.

e. Request five sought information on numbers of bodies donated to licensed anatomic establishments over the last five years in the United Kingdom.

f. Request six sought to know the percentage of bodies that are accepted by medical science establishments.

27. The HTA’s response to these and other FOIA requests are published on our [website].

Complaints report

28. The HTA received no complaints about the organisation since the Authority’s meeting on 4 May 2017.

Development

European Union Coding and Import Directives update

29. Following the announcement of the General Election, the Department of Health advised that given the seven week pre-election period in which Parliament was dissolved, the regulations required to implement the European Union Directives on Coding and Import could not now be approved before the start of Parliament’s summer recess (20 July 2017).

30. The decisions relating to the transposition of the Directives will therefore be for the incoming Government to make, following the General Election. The HTA will continue to work closely with colleagues at the Department on the transposition and we will provide further advice for establishments on the likely timetable and the process for re-issuing import licences. The HTA will draft directions as soon as we can, subject to the necessary ministerial and parliamentary approvals being obtained, in order to allow establishments to prepare ahead of implementation. In the interim, we have published updated guidance following feedback received during the consultation on our website.
Deployment

Corporate planning and reporting

31. Since the Authority meet on 4 May 2017, the HTA Management Group (HTAMG) has continued to review and refresh its approach to:

   a. providing assurance against its delivery of the 2017/18 Business Plan; and
   b. how it carries out its continuous business planning.

32. To support this, new reporting documentation has been put in place and guidance for project and activity-planning processes has been developed and shared. HTAMG has also carried out a review of its operational risk register against the new Business Plan, to ensure that it reflected recent updates to the strategic risk register.

33. In June, the following projects and activities were scoped for consideration by HTAMG:

   a. establishing a horizon scanning function at the HTA;
   b. reviewing the sustainability of the Independent Assessor framework;
   c. moving to a system of continuous accreditation for Independent Assessors; and
   d. developing a licensed establishment relationship programme.

34. HTAMG also reviewed final project documentation for a project to assess risks in the human application sector, with a view to updating our processes to reflect the findings of the project.

Personal Development Planning (PDP) for 2017/18

35. The HTA committed to reviewing its PDP process as part of the 2016/17 People Strategy following staff survey results, which identified that the majority of HTA staff did not feel the PDP process improved their performance.

36. A survey was conducted in April, which identified concerns relating to the format of the PDP discussions and a perception of low importance being placed on the future development element of the process.

37. This feedback was discussed at HTAMG, which resulted in changes being made to the PDP process to put more focus on development. We have also developed guidance and resource documents to help both line managers and staff to prepare for PDP discussions, in order to make them more beneficial.

38. We will conduct a further review at the end of 2017/18 to understand if these changes have addressed the concerns raised.
All staff meeting

39. On 12 June 2017, all HTA staff came together to discuss the development of the HTA’s strategy and various policy issues.

40. The Chair, who was present, spoke with colleagues about how the Authority would be seeking advice from SMT and colleagues to consider how the HTA’s strategy could change for the period 2018-21 in the run up to the Authority’s strategic away-day in October.

41. Colleagues heard the initial findings of the HTA’s recent public evaluation, and were presented with the early thinking behind a project that will consider risks in the human application sector.

42. Colleagues also discussed the operation of the staff forum, and celebrated notable achievements of particular staff members.

Department of Health accountability meeting update

43. On 24 May, Richard Sydee and I met with Mark Davies and Department colleagues for our annual accountability meeting. The meeting was positive about the HTA’s achievements in 2016/17, and no significant concerns were raised.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Overview: Risks reflect the strategy for 2016-19 (year two update published in April 2017 (2017/20 document)). SMT has downgraded the residual score of risk one to green. Our highest risk are now 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 fu and failure to utilise our capabilities effectively, which is currently affected by a key vacancy in our business technology.

Other notable risks: Final delivery of some of one of the HTA's key projects (Coding and Import) remains in part in the hands of others. The HTA can deliver our part but is not in control of actions necessary before implementation. Delays may affect the attitude of our stakeholders and the HTA's reputation. Further uncertainty is caused by Brexit and the changes in Government following the General Election.

A number of more recently recruited Regulation Managers are now approaching sign off and recruitment to key posts has now been completed. This will increasingly have a mitigating impact.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Apr 2017</th>
<th>May 2017</th>
<th>Jun 2017</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Failure to regulate appropriately (Risk to Delivery a-e and Development a-d)</td>
<td></td>
<td></td>
<td></td>
<td>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 organisations capability and strengthened our regulatory regime and recruitment for the one remaining RM vacancy has commenced.</td>
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<tr>
<td>2 - Failure to manage an incident (Delivery, Development and Deployment)</td>
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<td>Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 2016/17.</td>
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<tr>
<td>3 - Failure to manage expectations of regulation (Risk to Delivery d)</td>
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<td>We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DH 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 appears to the public as if it should be is challenging. The General Election has caused further delays in laying the regulations before parliament, although it is now certain that this will not be before September 2017, and some further uncertainty with regard to the approach a new administration will take to laying these regulations in relation to Brexit plans.</td>
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<tr>
<td>4 - Failure to utilise our capabilities effectively (Delivery a-d) (Development a-d) (Deployment a &amp; c)</td>
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<td>We continue to be in a position to use the skills of our newer recruits more fully. With the recent departure of the Head of Business Technology there is a significant gap in operational knowledge and capability around our IT infrastructure, recruitment is now complete and David Thompson will take up post on 10 July 2017. We anticipate 2017/18 development plans will be completed.</td>
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<td>5 - Insufficient, or ineffective management of, financial resources (Deployment b)</td>
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<td>At the start of the 2017/18 financial year we have a robust expenditure plan in place that will support our delivery plan. There is a minor shortfall in income due to a reduction in licensed activity beyond what is budgeted for and no confirmation at this time that DH will meet the costs of the increased rent costs at 151 BPR as they did in 2016/17.</td>
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</table>

Strategic Objectives

Delivery – to deliver the right mix of activity to main public and professional confidence
a) To 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 the public
b) To 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
c) To deliver effective regulation of living donation
d) To 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
e) To maintain our strategic relationships with other regulators operating in the health sector

Development – to make the right investment in development to continuously improve delivery
a) To reduce regulatory burden where risks to public confidence are lowest
b) To make it clear how to achieve compliance with new and existing regulatory requirements
c) To make continuous improvements to our systems and processes to minimise wasted or duplicated effort
d) To take opportunities to better inform and involve the public

Deployment – to make the most effective use of our people and resources in pursuit of our goals
a) To manage and develop our people in line with the HTA's People Strategy
b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
c) To provide a suitable working environment and effective business technology

Risks are assessed by using the grid below

<table>
<thead>
<tr>
<th>Impact</th>
<th>Lines of defence are</th>
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<tbody>
<tr>
<td>a. Catastrophic</td>
<td>1. Embedded in the business operation</td>
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<tr>
<td>b. Significant</td>
<td>2. Corporate oversight functions</td>
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<td>c. Moderate</td>
<td>3. Independent of the HTA</td>
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<td>d. Minor</td>
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<td>e. Almost None</td>
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</table>
### HTA (22a/17)

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting

<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK/PRIORITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK/PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tbody>
<tr>
<td>1</td>
<td>Risk to Delivery objectives a-c &amp; e Development objectives a-d</td>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate</td>
<td>3 4 Ongoing</td>
<td>Regulatory model</td>
<td>3 2</td>
<td>1 2 3</td>
<td>Preventive</td>
<td>Authority developed and approved the HTA Strategy</td>
<td>HTA Strategy published on 1 April</td>
<td>HTA Strategy published on 1 April and approved by the Department of Health</td>
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<tr>
<td></td>
<td>Risk Owner:</td>
<td>Allan Marriott-Smith</td>
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<td>Causes</td>
<td>• Failure to identify regulatory non-compliance</td>
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<td>• Regulation is not sufficiently agile to respond to changes in sectors</td>
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<td>• Failure to identify new and emerging issues within HTA remit</td>
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<td>People</td>
<td>HTA People Strategy roadmap 2017/18</td>
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<td>Specialist expertise identified at recruitment to ensure a broad range of knowledge across all sectors and in developing areas</td>
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<td></td>
<td>Quality management systems</td>
<td>HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</td>
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### Risk to Delivery objectives a-c & e Development objectives a-d

<table>
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<tr>
<th>Causes</th>
<th>Inherent Risk</th>
<th>Proximity</th>
<th>Existing Controls/Mitigations</th>
<th>Residual Risk</th>
<th>Actions to Improve Mitigation</th>
<th>Line of Defence</th>
<th>Type of Control</th>
<th>Assurance Over Control</th>
<th>Assured Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate</td>
<td>3 4 Ongoing</td>
<td>Regulatory model</td>
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<tr>
<th>People</th>
<th>Inherent Risk</th>
<th>Proximity</th>
<th>Existing Controls/Mitigations</th>
<th>Residual Risk</th>
<th>Actions to Improve Mitigation</th>
<th>Line of Defence</th>
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<th>Assured Position</th>
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</thead>
<tbody>
<tr>
<td>HTA People Strategy roadmap 2017/18</td>
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<td>Training and development of professional competence</td>
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### Other

<table>
<thead>
<tr>
<th>Other</th>
<th>Inherent Risk</th>
<th>Proximity</th>
<th>Existing Controls/Mitigations</th>
<th>Residual Risk</th>
<th>Actions to Improve Mitigation</th>
<th>Line of Defence</th>
<th>Type of Control</th>
<th>Assurance Over Control</th>
<th>Assured Position</th>
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<tbody>
<tr>
<td>Strengthening horizon scanning arrangements (VM) by Q4 2017/18</td>
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</table>

### Annex A: Risk Register

<table>
<thead>
<tr>
<th>Risk</th>
<th>Priority</th>
<th>Description</th>
<th>Control</th>
<th>Mitigation</th>
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<tbody>
<tr>
<td>A</td>
<td>High</td>
<td>Failure to identify regulatory non-compliance</td>
<td></td>
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<tr>
<td>B</td>
<td>Medium</td>
<td>Regulation is not transparent, accountable, proportionate, consistent and targeted</td>
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<tr>
<td>C</td>
<td>Low</td>
<td>Regulation is not sufficiently agile to respond to changes in sectors</td>
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<tr>
<td>D</td>
<td>Very Low</td>
<td>Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs))</td>
<td></td>
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<tr>
<td>E</td>
<td>Extreme</td>
<td>Inadequate adherence to agreed policies and procedures in particular in relation to decision making</td>
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<tr>
<td>F</td>
<td>Low</td>
<td>Poor quality or out of date policies and procedures</td>
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<tr>
<td>G</td>
<td>Very Low</td>
<td>Failure to identify new and emerging issues within HTA remit</td>
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<tr>
<td>H</td>
<td>Low</td>
<td>Failure to properly account for Better Regulation</td>
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<tr>
<td>I</td>
<td>High</td>
<td>Loss of public confidence</td>
<td></td>
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<tr>
<td>J</td>
<td>Medium</td>
<td>Compromises to patient safety</td>
<td></td>
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<tr>
<td>K</td>
<td>Low</td>
<td>Loss of respect from regulated sectors potentially leading to challenge to decisions and non-compliance</td>
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<tr>
<td>L</td>
<td>Very Low</td>
<td>Reputational damage</td>
<td></td>
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</tr>
<tr>
<td>REF</td>
<td>RISK/RISK OWNER</td>
<td>CAUSE AND EFFECTS</td>
<td>INHERENT RISK PRIORITY</td>
<td>PROXIMITY</td>
</tr>
<tr>
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</tr>
<tr>
<td>2</td>
<td>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</td>
<td></td>
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<tr>
<td></td>
<td>• 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)</td>
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<td></td>
<td>• caused by deficiency in the HTA’s regulation or operation</td>
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<td>• where we need to regulate, such as with emergency mortuaries</td>
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<td></td>
<td>• that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)</td>
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<td></td>
<td>Risk owner:</td>
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<td></td>
<td>Sarah Bedwell</td>
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<td></td>
<td><strong>Cause</strong></td>
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<td></td>
<td>• Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</td>
<td>5</td>
<td>3</td>
<td>Future, should event occur</td>
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<td></td>
<td>• Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)</td>
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<td></td>
<td>• Failure to work effectively with partners/other organisations</td>
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<td>• Breach of data security</td>
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<td>• IT failure or attack incident affecting access to HTA office</td>
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<td>Effect</td>
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<td></td>
<td>• Loss of public confidence</td>
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<td>• Reputational damage</td>
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<td>• Legal action against the HTA</td>
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<td>• Intervention by sponsor</td>
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<td><strong>Assessment</strong></td>
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<td><strong>Inherent Risk</strong></td>
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<td><strong>Priority</strong></td>
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<td><strong>Proximity</strong></td>
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<td><strong>Controls/Mitigations</strong></td>
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<td><strong>Residual Risk</strong></td>
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<td><strong>Actions to Improve Mitigation</strong></td>
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<td><strong>Line of Defence</strong></td>
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<td><strong>Type of Control</strong></td>
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<td><strong>Assurance over Control</strong></td>
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<td><strong>Assured Position</strong></td>
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<td><strong>Implementation</strong></td>
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</table>

**HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting**
<table>
<thead>
<tr>
<th>REF</th>
<th>INHERENT RISK OWNER</th>
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<th>CAUSE</th>
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<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tbody>
<tr>
<td>2</td>
<td>Failure to manage public and professional confidence in regulation of human tissue in particular stemming from limitations in current legislation or re-alignment of HTA regulatory reach</td>
<td>Risk to Delivery Objective d</td>
<td>External factors</td>
<td>Ongoing</td>
<td>Log of issues known to the HTA with respect to the legislation to inform DH and manage messages</td>
<td>4 4</td>
<td>Monitoring</td>
<td>X</td>
<td>Preventative</td>
<td>Stakeholder Group meeting includes Authority minutes (including Public Authority Meeting)</td>
<td>X Preventative</td>
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<td></td>
<td>Risk Owner: Vicky Marshment</td>
<td></td>
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<td></td>
<td>Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope</td>
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<td>Last stakeholder group meeting in May 2017, Authority meeting in May 2017</td>
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<td>Log of issues raised by the media – including the development of the HTA position on issues</td>
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<td>Last report in May 2017 - satisfactory</td>
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<td>Active management of issues raised by the media – including the development of the HTA position on issues</td>
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</table>

**Monitoring**

Regular reporting to DH sponsorship team on matters which risk public and professional confidence

**Log of issues**

Known to the HTA with respect to the legislation to inform DH and manage messages

**Active management of professional stakeholders**

Through a variety of channels including advice about relevant materials in and out of scope

---

**Preventative**

Draft policies may be subject to revision following the Authority meeting

HTA meeting papers are not policy documents.

---

**INHERENT RISK**

- **RESIDUAL RISK**

- **PRIORITY**

- **PROXIMITY**

- **EXISTING CONTROL/CATEGRISATION**

- **RESIDUAL RISK PRIORITY**

- **ACTIONS TO IMPROVE MITIGATION**

- **LINE OF DEFENCE**

- **TYPE OF CONTROL**

- **ASSURANCE OVER CONTROL**

---

**Risk to Delivery Objective d**

Risk Owner: Vicky Marshment

---

**External factors**

- No scheduled review of Human Tissue Act and associated regulations
- Rapidly advancing life sciences
- Potential move away from the UK as base for some regulated establishments due to Brexit and changes in exchange rates

---

**Issues which certain stakeholder groups believe require review**

- Scope of relevant materials e.g. waste products
- Licensing requirements e.g. transplantation research
- Regulation relating to child bone marrow donors
- Issues raised by emergence of social media e.g. non-related donors
- Strengthening of civil sanctions for non-compliance
- Implementation of the coding and award system in light of Brexit

---

**Matters which stakeholders/public may expect to be inside regulatory scope**

- Efficacy of clinical treatment from banked tissue
- Police holdings
- Products of conception and fetal remains
- Data generated from human tissue
- Funeral directors
- Forensic research facilities
- Cryopreservation
- Body stores / Taphonomy
- Imported material
- Other

---

**Effect**

- Diminished professional confidence in the adequacy of the legislation
- Redacted public confidence in regulation of matters relating to human tissue
- Reputational damage

---

**Circulation of principles within Code A to wider stakeholders to be undertaken**

**Quarter 1 2017/18**

**Preventative**

**Circulation of principles**

- To have policy in place DH comfortable with policy approach
- Implement regulatory changes, scheduling purposes and prevention

**End Q1 2017/18 - earlier if necessary**

**Cryopreservation**

**Development of guidance for public/professionals, as appropriate**

**End Q3 2017/18**

**Public research**

- Gaining a better understanding of public confidence and the factors which impact it
- Complete Q3 2017/18

---

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**HTA (22a/17)**
Failure to utilise people, data and business technology capabilities effectively
(Risk to Delivery objectives a-d, Development objectives a-c)

**Risk Owner:** Allan Marriott-Smith

### Inherent Risk

<table>
<thead>
<tr>
<th>REF</th>
<th>CAUSE AND EFFECTS</th>
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<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tbody>
<tr>
<td>4</td>
<td>People</td>
<td>4</td>
<td>3</td>
<td>People</td>
<td>4</td>
<td>3 X X</td>
<td>1</td>
<td>Preventive/ Monitoring</td>
<td>QMS reminders as policies due for review, SMR review of all revised policies</td>
<td>Currently in the middle of a regular review cycle</td>
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<td></td>
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<td>Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle</td>
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<td>Establish annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid-year review)</td>
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<td></td>
<td>Standards objectives for all line managers</td>
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<td>Regular review of HTA organisational structure and job descriptions</td>
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<td>Feedback from HTA people about work, management and leadership</td>
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<td>Data relating to establishments securely stored with the Customer Relationship Management System (CRM)</td>
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<td></td>
<td>Staff training in key business systems</td>
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<td>IT systems protected and assurances received from 3rd party suppliers that protection is up to date</td>
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<td></td>
<td>HTAANG Development schedule to be part of monthly meetings throughout 2017/18</td>
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<td>Range of projects within the People Strategy relating to managing and leading people, in particular more structured management and leadership training and development (AMS) by Oct/Nov 2017</td>
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<td>Plans to be developed (RS) by Q2 2017/18</td>
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<td></td>
<td>Identify refresher training and targeted software specific training needs (RS) by Q2 2017/18</td>
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### Effect

- Poor deployment of staff leading to inefficient working
- Disaffected staff
- Increased turnover leading to loss of staff
- Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed
- Poor use of technology resulting in inefficient ways of working
- Inadequate balance between serving Delivery and Development objectives

### People

- Lack of knowledge about individuals’ expertise
- Poor job and organisational design resulting in skills being under used
- Poor line management practices
- Poor project management practices
- Poor leadership from SMR and Heads
- Data holdings poorly managed and under-exploited
- Inadequate business technology or training in the technology available

### Data

- Lack of knowledge about individuals’ expertise
- Poor job and organisational design resulting in skills being under used
- Poor line management practices
- Poor project management practices
- Poor leadership from SMR and Heads
- Data holdings poorly managed and under-exploited
- Inadequate business technology or training in the technology available

### Business Technology

- Staff training in key business systems
- IT systems protected and assurances received from 3rd party suppliers that protection is up to date

###ami

- Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed
- Poor use of technology resulting in inefficient ways of working
- Inadequate balance between serving Delivery and Development objectives
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
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<th>ASSURED POSITION</th>
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<tbody>
<tr>
<td>5</td>
<td>Insufficient, or ineffective management of, financial resources (Risk to Deployment objective b) Risk Owner: Richard Sydee</td>
<td><strong>Cause</strong></td>
<td>4 4</td>
<td>Ongoing</td>
<td><strong>Budget management framework to control and review spend and take early action</strong></td>
<td><strong>3 4</strong></td>
<td>X X</td>
<td><strong>All</strong></td>
<td><strong>Budgattary control policy reviewed annually and agreed by SMT</strong></td>
<td><strong>Last review February 2017</strong></td>
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<td></td>
<td></td>
<td><strong>Effect</strong></td>
<td>4 4</td>
<td>Monitoring</td>
<td><strong>Financial projections, cash flow forecasting and monitoring</strong></td>
<td><strong>X</strong></td>
<td><strong>Monitoring</strong></td>
<td><strong>Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH</strong></td>
<td><strong>Last quarterly report March 2017</strong></td>
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<td>4 4</td>
<td>Preventative</td>
<td><strong>Rigorous debt recovery procedure</strong></td>
<td><strong>X</strong></td>
<td><strong>Preventative</strong></td>
<td><strong>Annual update to fees model</strong></td>
<td><strong>Update agreed by the Authority November 2016</strong></td>
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<td>4 4</td>
<td>Monitoring</td>
<td><strong>Reserves policy and levels reserves</strong></td>
<td><strong>X</strong></td>
<td><strong>Monitoring</strong></td>
<td><strong>Reserves policy reviewed annually and agreed by ARAC</strong></td>
<td><strong>Last agreed February 2017</strong></td>
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<td>4 4</td>
<td>Preventative</td>
<td><strong>Delegation letters set out responsibilities</strong></td>
<td><strong>X X</strong></td>
<td><strong>Preventative</strong></td>
<td><strong>Delegation letters issued annually</strong></td>
<td><strong>Issued in April 2016</strong></td>
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<td></td>
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<td>4 4</td>
<td>Preventative</td>
<td><strong>Prioritisation when work requirements change</strong></td>
<td><strong>X</strong></td>
<td><strong>Preventative</strong></td>
<td><strong>Agreed business plan, monthly HTAMG and SMT reports</strong></td>
<td><strong>Last HTAMG report May 2016</strong></td>
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<td>4 4</td>
<td>Monitoring</td>
<td><strong>Fees model provides cost/income information for planning</strong></td>
<td><strong>X</strong></td>
<td><strong>Monitoring</strong></td>
<td><strong>Annual review of fees model, reported to SMT and Authority</strong></td>
<td><strong>Update agreed by the Authority November 2016</strong></td>
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<td>4 4</td>
<td>X</td>
<td><strong>Annual external audit</strong></td>
<td><strong>X</strong></td>
<td><strong>Detective</strong></td>
<td><strong>NAO report annually</strong></td>
<td><strong>Last report in May 2016 - clean opinion</strong></td>
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<td>4 4</td>
<td>X</td>
<td><strong>Monitoring of income and expenditure (RS) Ongoing</strong></td>
<td><strong>X</strong></td>
<td><strong>Detective</strong></td>
<td><strong>Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH</strong></td>
<td><strong>Last quarterly report March 2017</strong></td>
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<td>4 4</td>
<td>X</td>
<td><strong>Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) Ongoing</strong></td>
<td><strong>X X</strong></td>
<td><strong>Detective</strong></td>
<td><strong>Quarterly Finance Directors and Accountability meetings</strong></td>
<td><strong>Last FDs meeting Dec 2016</strong></td>
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Audit and Risk Assurance Committee update

Purpose of paper

1. This paper provides an overall assessment of items discussed at the 18 May 2017 meeting of the HTA’s Audit and Risk Assurance Committee (ARAC), and ARAC’s report of annual activity at Annex A.

2. This is a regular report to the Authority, which is provided three times per year at the Authority’s meetings following ARAC meetings.

3. ARAC provides an annual report of its activities to the Authority in line with good practice.

Decision-making to date

4. This paper, the annual report of ARAC activity and the minutes of the 18 May 2017 meeting have been agreed by Amanda Gibbon, Chair of ARAC.

Action required

5. The Authority is asked to note the content of this paper.
18 May 2017 Meeting

Annual report and accounts

6. Richard Sydee, Director of Resources, presented the 2016/17 Annual Report and Accounts to the Committee, providing an overview of the material changes in the accounts when compared to the 2015/16 accounts. The Committee discussed the content of the annual report, requesting some minor amendments.

7. George Smiles, The National Audit Office’s appointed Audit Director for HTA, confirmed that the audit of the 2016/17 financial statements was substantially complete. He anticipated being able to recommend the certification of the 2016/17 financial statements, with an unqualified audit opinion, to the Comptroller General for sign-off.

8. Members of the Committee congratulated the Resources Directorate on the provisionally unqualified certification of the financial statements and recommended that the HTA Accounting Officer approve the 2016/17 Annual Report and Accounts.

Audit tracker

9. Morounke Akingbola provided the Committee with an update on the progress against the recommendations from recent Internal Audit reports. The Committee noted the progress and was content that issues were being appropriately addressed.

Internal audit

10. Paul Foreman, from the outgoing Internal Auditors PwC, presented the findings and recommendations arising from the recent Crisis Management Exercise and Quality Governance Advisory Review.

Crisis Management Exercise

11. The Committee was advised to accept limited assurance on the HTA’s arrangements for crisis management and that the report contained the actions agreed with HTA’s senior management team (SMT).

12. It was suggested that the limited assurance concluded by the auditor was quite a severe judgement in the context of the HTA’s size and remit. Allan Marriott-Smith and Sarah Bedwell acknowledged the auditor’s findings as being fair. They assured Members that the limited scope and timing of the exercise had been a deliberate consideration designed to test the organisation’s capacity to respond to a likely scenario.
Quality Governance Advisory Review

13. The Quality Governance Advisory Review was undertaken as an assurance-mapping workshop to gather management feedback on the controls in place to address agreed line management and licence management processes. Given the lack of detailed testing involved in this exercise, Auditors did not provide an assurance rating but did identify a number of low priority recommendations.

14. Members commended SMT for the candour of its response to the recommendations and its confidence in the existing management arrangements or initiatives to address these issues.

15. The Committee noted the findings, recommendations and management responses arising from the above assurance reports.

Internal Audit Annual Assurance Report 2016/17

16. Paul Foreman presented an overview of the Internal Audit Annual Assurance Report 2016/17. This Report included the Internal Auditor’s opinion on the HTA governance, risk management and internal controls, which informs the HTA’s Annual Governance Statement.

17. The Internal Auditors had concluded that they could give moderate assurance to the HTA Accounting Officer that the HTA had effective systems of governance, control and risk management in place for the reporting year 2016/17.

18. The Committee noted and approved the report.

2017/18 Internal Audit Plan

19. Jeremy Nolan, HTA’s Head of Internal Audit from 1 April 2017, presented the draft 2017/18 Internal Audit Plan for consideration and approval by the Committee. The Committee was advised that the draft plan had been aligned to the HTA’s strategic risks and had already been approved by the HTA’s SMT.

20. The Committee heard from the Director of Resources who outlined the requirement to conduct an audit of financial controls in his first year in post. There will be a review of the overall control environment and a specific review of the budget setting and income forecasting processes.

21. The Committee approved the proposed 2017/18 Audit Plan subject to minor changes to scope and scheduling of the Cyber Security and Stakeholder Engagement activities.
Risk update

22. The Committee reviewed the HTA’s Strategic Risk Register, noting that this was an updated version to that provided to the recent Authority meeting. The Committee noted that the Director of Resources had reviewed strategic risk five, in consideration of the entirety of the HTA’s budget setting process. This resulted in a change to the risk, to ensure the ongoing viability of the HTA’s financial position.

Policy and procedure update

Policy updates

23. The Committee received the following updated policies for approval:

a. HTA Risk Management Policy and Strategy;
b. HTA Anti-Fraud, Corruption and Bribery Policy;
c. HTA Gifts and Hospitality Policy and Register; and
d. HTA Risk Interdependencies Update.

24. Members approved the policies with minor amendments. Members noted the entries in the Gifts and Hospitality Register and agreed that they would review a rolling annual register at each committee meeting. Members also asked managers to circulate a copy of the updated Gifts and Hospitality Policy to all Authority Members.

Information Risk Management

25. Members reviewed and agreed the Senior Information Risk Owner’s (SIRO) annual assessment of the HTA’s information risk management arrangements, noting the SIRO’s self-assessment of HTA compliance with the mandatory requirements of the Government’s Security Policy Framework 2014.

26. Members asked for assurance on the potential threat of staff, Authority and other associates of the HTA logging into the HTA’s systems, from hardware containing older / out of date software.

Actions to Address the 2016 Caldicott Review

28. The Committee noted the HTA’s assessment of the 2016 Caldicott recommendations and that no substantive changes would be required to the HTA’s information assurance framework.

**Breadth of activity, regulatory approach and risk assessments for various aspects of the human application sector**

29. Robert Watson, Head of Regulation (Human Application) presented a paper on the current approach to regulation within the sector.

30. Members explored the risks associated with the human application sector, asking a number of detailed questions in relation to the current and future risks. Members thanked Robert for his detailed paper and the level of assurance he had provided to the Committee. The Committee asked management to consider and report back on the following areas:

   a. How the Department of Health would support the HTA and other health-based regulators in the absence of the European Union based for a, lost as a result of ‘Brexit’.
   b. Investigate the availability of any National Institute of Health Research programmes that might enable the HTA to gain access to scientific journals.

**Regular reporting update**

31. Richard Sydee assured Members that there were no instances of grievance, dispute or fraud to report for this item.
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting
Annex A

Report of the Audit and Risk Assurance Committee Activity 2016/17

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

2. Membership of the Audit and Risk Assurance Committee (ARAC) through the year has been:

   a. Amanda Gibbon (ARAC Chair from 5 May 2016);
   b. Catherine Seddon (ARAC Chair and Authority Member until 4 May 2016);
   c. Dr. Stuart Dollow (ARAC Member from February 2017);
   d. Prof. Andy Hall;
   e. William Horne; and
   f. Glenn Houston.

3. The membership of ARAC changed in May 2016 due to Members’ terms of appointment coming to an end. The Chair of the Authority, Sharmila Nebhrajani, attended the May 2017 meeting.

4. ARAC met three times in 2016/17. The Chief Executive, the Director of Resources, the Head of Finance and Governance, the HTA’s external and internal auditors and a representative of the Department of Health attended meetings. Other directors and staff attended to discuss particular risk areas that ARAC wished to explore, or other topics depending on the ARAC’s business. ARAC’s terms of reference outline the support this body provides to the Accounting Officer (the Chief Executive) throughout the year, in particular by providing scrutiny to support the agreement of the Governance Statement.

Role and function

5. ARAC’s formal role is to advise the Accounting Officer and Authority on:

   a. the strategic processes for risk, control and governance and the Annual Governance Statement;
   b. the accounting policies, the accounts, and the annual reports of the HTA, levels of error identified, and management’s letter of representation to external auditors;
   c. the planned activity and results of both internal and external audit;
   d. adequacy of management response to issues identified by audit activity, including external audit’s audit completion report;
e. assurance relating to corporate governance requirements for the HTA; and
f. policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations.

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

Review of Committee effectiveness

7. The Committee reviewed its effectiveness in the period February 2016 to February 2017. This consisted of members responding to a series of questions relevant to ARAC at this time. The questions were:

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

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

9. The ARAC Chair and Committee Members attended Department of Health and National Audit Office (NAO) events, including networking meetings of audit committee chairs.

Risk Management

10. Strategic risks are reviewed by the Senior Management Team (SMT) on a monthly basis and are reported to the Authority quarterly. In May 2017, SMT reviewed the strategic risks facing the HTA. It came to a view that strategic risks one to four should remain unchanged, but that strategic risk five should be broadened to consider more widely the external risk factors to reflect both the risk of raising insufficient finance to
fund the HTA in 2017/18 and beyond and also that the risks that its financial controls are inadequate, or SMT makes inappropriate decisions about allocating finances.

11. The Committee reviewed the updated register at its May 2017 meeting. During the year, the Committee also identified risk areas to explore in greater detail and relevant staff attended Committee meetings to provide more information and assurance on:

   a. reduced income from licence fees in the post-mortem sector;
   b. the HTA’s approach to staff turn-over; and
   c. risks in the human application sector and public confidence in HTA regulation.

12. The Committee discussed in some detail the revisions to HTA’s risk management policy, with a particular focus on appetite and tolerance of risk and the need to consider risk interdependency with the Department of Health and the wider network of the Department’s arm’s length bodies. The Committee approved a revised version of this policy at its May 2017 meeting.

**Information and data security**

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

14. The SIRO is obliged to provide an assessment of information risk management to the Accounting Officer annually. This Report underpins the information included in the HTA’s Annual Governance Statement and is also a key reporting tool for the Department of Health and the Cabinet Office. The Report is also made to ARAC, so that the Committee is updated on any matters arising in this area.

15. The assessment is made against the Cabinet Office’s HMG Security Policy Framework (SPF), which outlines the requirements and management arrangements to which all departments and arm’s length bodies must adhere. The SIRO’s Report also includes an assessment of how the HTA meets the suggested steps to cyber security.

16. During the year, the Committee agreed the SIRO’s Report for 2016/17. This Report stated that the HTA applied the requirements in a form that is proportionate with HTA work and risk. No data losses were identified and the SIRO considered that information risk was managed adequately. For the relevant requirements in the SPF, there were no areas of non-compliance that put information security at risk.

17. The SIRO also reviewed the most recent report and recommendations from Dame Fiona Caldicott. The Committee agreed with the assessment that where those
recommendations do apply to the HTA, the SPF provides a suitable assessment against those risks.

18. The Report assessed the risk to the HTA’s cyber security overall as amber, due to the significant impact should an attack be made. The likelihood of an attack is possible. The HTA continued to monitor the situation and took steps that are possible to protect against a cyber-attack, with an emphasis on making sure staff are aware of the risks and act accordingly.

Internal audit

19. During 2016/17, the HTA had a Service Level Agreement with the Department of Health, for internal audit services to be provided by PwC. The Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress. During the year, the Head of Internal Audit and the Audit Manager changed.

20. There were no high priority findings during the year. The Committee concluded that management has responded positively to audit findings and recommendations and has taken, or is in the process of taking, action to implement agreed recommendations from Internal Audit Reports.

21. Internal Audit gave “moderate” assurance that the HTA had adequate and effective systems of control, governance and risk management in place for the reporting year 2016/17.

22. The Committee appointed the Government Internal Audit Agency as HTA’s Internal Auditor from 1 April 2017. The Committee reviewed and approved an audit plan for the upcoming financial year.

External Audit

23. NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2015/16 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

Assurance processes

24. During 2016/17, the Chief Executive met with HTA Directors at least monthly (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to approve policies, review exceptions, identify and act on lessons learned.
25. The Committee believes that ongoing management review and communication, supported by the findings of audits and Departmental oversight gives sufficient evidence to provide the Accounting Officer with assurance that the systems are sufficiently robust, and that the exceptions are relatively insignificant.

Governance statement

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

Summary

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

Amanda Gibbon, Chair, Audit and Risk Assurance Committee, on behalf of the Audit and Risk Assurance Committee

June 2017
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
2016/17 Advisory Groups Update

Purpose of paper

1. This paper provides an update on the work of the HTA’s advisory groups over the 2016/17 year.

Decision-making to date

2. This paper was signed-off by the Senior Management Team (SMT) on 15 June 2017.

Action required

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

Stakeholder and Fees Group

Constitution and core functions

4. The HTA established the Stakeholder and Fees Group to provide a forum for regular consultation on our approach to regulatory activities, including fee-setting and an opportunity for stakeholders to make their views known to the Authority.

5. The Group ensures that the HTA continues to improve transparency and accountability and maintain effective working relationships with the establishments we license.
6. Its members contribute to the development of our thinking on new initiatives across all sectors, helping to ensure that we understand the demands stakeholders are facing and that stakeholders have confidence in our decisions.

7. The Group has three main functions:
   
   a. to provide an ongoing channel of communication with stakeholders;
   b. to provide a forum for regular discussion of regulatory issues; and
   c. to consider fees proposals annually.

Programme of work on the relationships we have with people working at licensed establishments

8. The Group has had input into the development of the HTA’s relationships programme for licensed establishment. This was initially focussed on developing the HTA’s relationships with Designated Individuals (DIs). However, this focus was changed following feedback from the Group, as well as from a group of DI volunteers and HTA staff. The programme of work has been expanded to include all staff working at licensed establishments.

9. At the Group’s meeting in May 2017, it discussed the projects which make up this programme of work. It was agreed that the highest priority should be to pull together a package of training resources for new DIs. These will be available on the HTA’s website before the end of June 2017.

10. The HTA will continue to seek the Group’s feedback into this programme of work as it develops.

11. Because of the range of members on the Group, it can be challenging to find topics which share a common ground and / or affect the majority of members. At its October 2016 meeting, the Group discussed how it could best provide value to the HTA, as well as to stakeholders. The following themes were suggested by the group:
   
   a. Cross-sector activity - e.g. areas of overlap between different licensed sectors, such as consent issues.
   b. Public engagement - e.g. to help the HTA reach a wider group of stakeholders through members’ communications channels.
   c. Regulatory issues - e.g. how to respond to common regulatory findings across sectors.
   d. Ongoing dialogue - e.g. the development of online facilities to maintain engagement between the HTA and stakeholders.

12. These areas of focus will be re-visited following a wider review of the HTA’s advisory groups.
Stakeholder involvement

13. The Group has had input into a number of areas of HTA work over the last year. This includes the development of policies and guidance, as well new HTA processes, such as:

a. A joint HTA / Medicines and Healthcare products Regulatory Agency inspection - The joint inspection was carried out at an NHS Blood and Transplant (NHSBT) site in Liverpool. Representatives from both the HTA and NHSBT gave their views on the inspection at the May 2017 meeting. Both organisations learnt from the experience and agreed they would benefit from further joint inspections.

b. HTA’s Representations process - The revised process received positive feedback from the Group and continued to support the HTA first step of engaging with licensed establishments when differences exist.

c. Codes of Practice and Standards - The Group discussed the plans for reviewing the implementation of the Codes and Standards and was asked to raise any issues or areas for improvement.

d. Lay guides to the Codes of Practice and Standards - The Group provided feedback for the draft versions of lay guides, which support the HTA’s updated Codes of Practice and Standards. This feedback follows input from the HTA’s public review panel.

Review of 2017/18 fees

14. The HTA consulted on licensing fees for 2017/18 between 25 July and 30 September 2016. Following this, the Group discussed the consultation responses and a finalised proposal.

15. The discussion focused on the HTA’s policy decisions and underlying assumptions, which affect overall fees. These included:

a. the effort required to inspect different establishments (transplant centres for one organ versus multi-organ centres, which take more resources to inspect);

b. the potential for greater interaction with the HTA to lead to increased fees; and

c. the HTA’s ability to review underlying assumptions, as the validity of these will likely change in future, and also how work undertaken on these assumptions may impact the 2018/19 fees.

16. Overall, the Group supported the proposed changes. In particular, it agreed with the proposal to increase the HTA’s budget to allow for increased staff and information technology development.
Histopathology Working Group

Constitution and core functions

17. The Histopathology Working Group (HWG), in its current form, was established in 2010. It meets twice a year, in the spring and the autumn, and has four core functions:

   a. to maintain strategic oversight of the sector;
   b. to provide a forum for debate on sector-specific issues and inform implementation of resulting work streams;
   c. to consider standards documents and other guidance on the investigation of death created by the Royal College of Pathologist's (RCPath) Death Investigation Group;
   d. to report back to the Authority on key issues as necessary.

18. Standing agenda items include updates from the HTA and RCPa th. In addition, the HTA and RCPath identify topics for discussion, in response to current issues.

19. HWG is a working group rather than a decision-making group, which has a history of achieving tangible outputs based on a shared purpose and agreement of key issues facing the post-mortem sector.

Sector specific issues

20. In 2016/17, HWG discussed a range of topics, including:

   a. the growing shortage of pathologists to undertake post-mortem work;
   b. the Royal College of Surgeon's (RCS) Pathology Collections Specialist Subject Network;
   c. the All-Party Parliamentary Group for Funerals and Bereavement into delays between death and burial or cremation;
   d. the Ministry of Justice and Department of Health consultation on Medical Examiners and reforms to death certification;
   e. The Health and Safety Executive (HSE) guidance on managing the risks of infection in the mortuary;
   f. HTA joint inspections with the United Kingdom Accreditation Service (UKAS);
   g. mass fatalities and the management of tissue samples;
   h. DI training; and
   i. aspects of mortuary practice.
21. Actions that were agreed during 2016/17 include:

a. changes to RCPath’s guidance on brachytherapy of the prostate using implantation of radioactive seeds;
b. the production of an article on the Royal College of Surgeon’s project in the RCPath newsletter;
c. co-ordinated responses by RCPath, the Association of Anatomical Pathologists and HTA to the consultation on medical examiners;
d. the provision of advice to the HSE on the use of body bags and face-fitted masks;
e. a statement from RCPath on UKAS inspection of mortuaries; and
f. clarification of the Government’s work on mass fatality planning and the management of human remains.

22. At HWG’s May 2017 meeting, results of the survey carried out to assess the effectiveness of HWG were fed back to members. Respondents were unanimous in their view that HWG is effective in maintaining strategic oversight of the post-mortem sector, with individuals commenting on its value as a means of horizon scanning and recognising that the diversity of its members makes for worthwhile and informative debate on key issues.

Transplantation Advisory Group

Constitution and core functions

23. The HTA established the Transplantation Advisory Group (TAG) as a forum for the discussion of issues arising in living and deceased organ donation, in particular:

a. discussion of new policy issues and emerging novel areas in transplantation;
b. identification of revisions required to current HTA or NHSBT policies;
c. discussion on the complex ethical issues in transplantation in order to ensure the requirements of the Human Tissue Act 2004 and associated regulations are met;
d. reviewing guidance on issues surrounding Independent Assessors (IAs), including recruitment and performance issues identified during the reaccreditation process.

24. TAG maintains strategic oversight of living organ donation and provides a useful check and challenge for the HTA’s decision-making processes. It provides a forum for debate on sector-specific issues to inform policy decisions and allows Authority Members that are part of the group to report to the Authority on key issues, as necessary.
Strategic overview of the living donation sector

25. The living donation sector continues to evolve, particularly with the expansion of the National Kidney Sharing Schemes. Although living donation numbers have plateaued in the last year or two, successful matches as a result of this scheme mean more patients are benefitting from a living donor transplant via this route. From an HTA perspective, this means there has been an increase in the numbers of living donation applications being referred to a panel of three Authority Members for decision, as this is required by law.

Policy issues and emerging novel areas of transplantation

26. This area continues to evolve with novel forms of transplantation emerging. In terms of donation from deceased donor’s, discussions amongst professionals are ongoing about uterine donation and the practicalities of implementing a programme in the United Kingdom for a very specific group of patients.

Review of Guidance to transplant teams and Independent Assessors

27. The Guidance to transplant teams and Independent Assessors was last published in March 2015. This is currently under revision and will be published by the end of quarter two.

Review of the Advisory Groups

28. During quarter two, the HTA will carry out a review of the three advisory groups. This review will consider whether we have in place the advisory groups necessary to support our policy and process development, and to foster relationships, which drive increased compliance, in turn delivering increased public confidence in HTA regulation.

29. The review also aims to identify operational best practice and any standardised processes that could drive greater efficiency and effectiveness. This will build on surveys undertaken by two of the three groups, with a view to implementing any changes by the time the groups next meet in quarter three.
HTA Strategic Review 2018 to 2021

Purpose of the paper

1. To set out, at a high level, the scope and timetable for the annual review of the HTA’s Strategy.

Decision-making to date

2. The Senior Management Team (SMT) agreed the proposed scope of the review at meetings on 8 and 15 June, although no formal decisions have been made. The HTA’s strategic direction will be agreed when the Authority meets on 19 October 2017.

Action required

3. The Authority is asked to review the paper and provide any comment on scope and timing.

Background

4. The Chair has a particular responsibility for providing effective leadership for the Authority on the formulation of its Strategy, as set out in the Code of Conduct for Members. Though, as the Authority’s Standing Orders set out, it is the Chief Executive who prepares a three-year strategy each year, and annual business plan for the Authority to approve.

5. For the review in this business year, SMT and the Authority have agreed to undertake a fundamental evaluation of the extent to which our current strategic approach protects
public and professional confidence and, as a result, develop proposals for changes that may be required for the Strategy covering 2018 to 2021.

6. The Authority had an initial discussion about the Strategic Review at its meeting on 4 May. The outline of the review, as amended following the meeting is attached at Annex B.

7. In reviewing the overall Strategy, the Authority will need to consider three interdependent issues:

   a. How does our current Strategy need to be adapted to best protect public and professional confidence (and over what time period)?
   b. How (if at all) does the fees model need to be adapted to accommodate and change in Strategy?
   c. Does any change to the Strategy require fundamental revisions to the People Strategy?

8. The Executive aims to be in a position to advise the Authority on these matters and to provide a steer on the various options by the time of the Authority strategic away day on 19 October 2017.

9. SMT held planning sessions on 8 and 15 June to come to a common view about scope so that any necessary analysis that is not already commissioned can be undertaken over the summer.

Scope and products

10. At a high level, the aim for the 19 October is for the Authority to be in a position to answer the question: Does the HTA strategy, especially the regulatory model in the delivery theme, provide optimum protection of public and professional confidence?

11. To allow the Authority to answer this question in a meaningful way, the Executive will provide a document with a set of proposals for change for discussion and agreement of a way forward.

12. This document will be supported by a series of annexes, which provide the evidence base for these proposals. Our proposed draft structure for this document is set out in Annex A.
13. The timetable below sets out milestones in advance of the October meeting and beyond.

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Timing</th>
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<tbody>
<tr>
<td>Agreement of scope and timing</td>
<td>Authority meeting 28 June</td>
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<tr>
<td>Development of evidence base</td>
<td>June to mid-September</td>
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<tr>
<td>Status update on Strategy Review Paper</td>
<td>Paper provided for Authority meeting on 14 September</td>
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<tr>
<td>Analysis of evidence and finalising</td>
<td>Throughout September 2017</td>
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<tr>
<td>proposals</td>
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<tr>
<td>Proposal document with annexes</td>
<td>By 5 October 2017</td>
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<tr>
<td>circulated to the Authority</td>
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<tr>
<td>Stakeholder Group Meeting – including</td>
<td>18 October 2017</td>
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<td>discussion about indicative fees</td>
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<tr>
<td>Authority Strategic Away day</td>
<td>19 October 2017</td>
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<tr>
<td>Budget and fees development</td>
<td>By end December 2017</td>
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<tr>
<td>Review of People Strategy</td>
<td>January to March 2018</td>
</tr>
<tr>
<td>Publication of revised Strategy</td>
<td>2 April 2018</td>
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HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting
Annex A

Proposal for change – Draft report structure

The Executive plans to provide the Authority with proposals for change structure along the following lines.

Providing optimum protection of public and professional confidence 2018 to 2021

Section 1 – Proposed changes to the Delivery model

a. Risk-based allocation of resources between regulated sectors.
b. Risk-based allocation of resources within regulated sectors:
   i. Human application sector proposals – segmentation and use of regulatory tools
   ii. Applicability of human application proposals in other sectors.
c. Managing emerging policy issues.

Section 2 – Implications of Delivery proposals for Development projects

d. Relative priority and timing of proposed change projects.

Section 3 – Implications for Deployment of resources

e. Implied budget requirements for 2018/19 and beyond.
f. Implications of fee structure.
g. Next steps on People Strategy 2018 and beyond.
h. Estates to 2021
   i. Business Technology and data management priorities.

Annexes:

- Detailed findings from HA risk project (outputs mid-September)
- Public Evaluation Report (outputs early Summer)
- HTAMG / Staff views on strategic issues (summary findings late Summer)
- View from licenced establishments (Public Authority meeting onwards)
HTA meeting papers are not policy documents.
Draft policies may be subject to revision following the Authority meeting
**HTA Strategy 2018 – 2021**  
(Published April 2018)  
(Strategic themes subject to review)

**Direction of travel**

**Authority Strategic Away Day** (19 October 2017)

**Strategic questions for the Away Day**

- Does the HTA strategy, especially the regulatory model in the delivery theme, provide optimum protection of public and professional confidence?
- How does the organisation need to change by 2021?

**Resources available for the Strategic Away Day** (19 October 2017)

**What data are we missing that would better allow us to answer these questions?**

**Questions for the HA risk project**

Does the HTA lend itself to segmentation, including to individual establishment level, on the basis of risk to patient safety & public confidence (dimensions; public/private; complexity; licensable activity; others)...

...to the extent that a more tailored approach could be taken on a 2-yearly basis?

On either a segmented or unsegmented basis is there evidence to suggest we...

...could be using existing tools to better mitigate risks, e.g. wider use of unannounced inspections?

...could be using tools new to us to better mitigate risks, e.g. mystery shopping, observation of practice?

**Current regulatory model resources**

**Current delivery model (licensing and inspection)**

- Described in the Delivery section of our strategy to 2019.
- Described in the document setting out our inspectional rationale.
- Compliance updates set out in Directions.

**More risk**

<table>
<thead>
<tr>
<th>Licensing</th>
<th>PM</th>
<th>ODT</th>
<th>Research</th>
<th>PD</th>
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<tr>
<td>Procurement</td>
<td>Removal</td>
<td>Donation Activities</td>
<td>Storage</td>
<td>Storage</td>
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<td>Testing</td>
<td>Storage</td>
<td>Transplantation Activities</td>
<td>Removal (3 licences)</td>
<td>Use for Public Display</td>
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<td>Making of a PM</td>
<td>Examination</td>
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<td>Compliance updates (Biennial)</td>
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<td>Activity Data collection (annual)</td>
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**Less risk**

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<th>Anatomy</th>
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<tr>
<td>Removal</td>
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<tr>
<td>Carrying out of an AE</td>
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</table>

**Number of licences**

- 143 main sites
- 19 Hubs + 50 satellites
- 124 stand alone

- 183 main sites
- 52 hubs + 68 satellites
- 131 stand alone

- 38 main sites
- No satellites
- 103 stand alone

- 154 main sites
- 51 hubs + 135 satellites
- 10 stand alone

- 14 main sites
- 4 hubs + 6 satellites
- 10 stand alone

- 38 main sites
- 8 hubs + 16 satellites
- 30 stand alone

**Sector inspection risk rating/ frequency**

- High (50% of sector inspected every year) Ave. 72 inspections per annum
- Statutory max. 2 years between inspections

- Medium/high (35% of sector inspected every year) Ave. 50 inspections per annum
- Medium/high (35% of sector inspected every year) Ave. 12 audits per annum

- Low (10 - 15% of sector inspected every year) Ave. 20 inspections per annum
- Low (10 - 15% of sector inspected every year) Ave. 3 – 5 inspections per annum

**High level rationale**

- Risk to patient safety
- Complex and diverse sector

- Higher incidence of non-compliance
- High impact when things go wrong
- Major shortfalls relating to premises

- Risk to patient safety
- Good compliance

- Good compliance
- Risks less focussed on premises
- HTA limited role in licensing research

- Good compliance
- Static collections
- All new exhibitions inspected prior to opening

- Good compliance
- Small sector - close network that shares learning

**Incident reporting**

- SAERs
- HTARs

**Other regulators/ bodies**

- MHRA
- CQC
- RCPath
- Coroners
- Home Office
- NHSBT (Assisted Functions)
- CQC
- NHS England
- HRA
- Arts Council
- Anatomy Associations Advisory Committee

**Advice and guidance**

- Enquiries
- RASRM

**Plans for a future regulatory model**

**Future regulatory model for licensing and inspection**

- Proposals for the model as a whole from SMT/ HTAMG.
- Proposals for HA sector from the HTA risk project.
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Draft policies may be subject to revision following the Authority meeting.
Understanding risk in the human application sector

Purpose of paper

1. To inform the Authority about a project being undertaken to understand risk in the human application sector. A project overview is attached at Annex A.

2. This paper is accompanied by a presentation, which will be delivered at the meeting.

Decision-making to date

3. The project plan was presented to the HTA’s Management Group (HTAMG) at its October 2016 meeting, for approval.

4. The project overview document was presented to HTAMG on 15 June 2017.

Action required

5. The Authority is asked to note the content of this paper.

Background

6. This project will consider ways in which the HTA can target its regulatory approach in the human application sector, on the basis of risk to both patient safety and to public confidence.
7. The outcome of the project will be proposals on a future delivery model, aimed at delivering a more risk-based regulation of the human application sector. This will be delivered as recommendations to the Authority at the start of quarter three.

8. The resource required to deliver this project is dependent on the operational delivery and implementation of the European Union Import and Coding Directives. If the Government makes the decision to implement the Directives ahead of the summer recess, we will need to work through the impact on the deliverables and the timeline for this project.
## HTA Project Overview

### Project description

<table>
<thead>
<tr>
<th><strong>Project Name</strong></th>
<th>Risk in the Human Application Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Sponsor</strong></td>
<td>Victoria Marshment</td>
</tr>
<tr>
<td><strong>Project Manager</strong></td>
<td>Amy Thomas</td>
</tr>
</tbody>
</table>

The name by which the project will be known.

Director or Head who supports the business case and will take overall ownership of delivery of the project.

Person who will be responsible for ensuring the project will be delivered to time, cost and quality on a day-to-day basis.

### Purpose: Management and information

The project description document provides the information needed to manage a project and ensure that it is still on track. It describes the structure of the project and outlines the stages and which work packages are expected to be completed in which stage.

In addition, project risks and key milestones are captured in this document. It can also be used to provide a check list to talk through at project meetings. Risks should be assessed and updated at each meeting and milestones, work packages and stages can be updated at each meeting.

It also allows for additional notes from those meetings including key decisions, actions and exceptions should be recorded and tracked.

Simple projects may not need a separate project plan as long as the Milestones section in this document contains the appropriate level of detail.

Work packages listed in this document should have an accompanying work package description and any additional stages will need an accompanying stage justification document and approval from HTAMG to proceed. Work package descriptions only need to be completed in detail for the stage currently under consideration.

### Document information

<table>
<thead>
<tr>
<th><strong>Date</strong></th>
<th>June 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Author</strong></td>
<td>Dr. Amy Thomas</td>
</tr>
<tr>
<td><strong>Reviewed by</strong></td>
<td>Vicky Marshment</td>
</tr>
<tr>
<td><strong>Approved by</strong></td>
<td>HTAMG</td>
</tr>
<tr>
<td><strong>Version</strong></td>
<td>0.1</td>
</tr>
<tr>
<td><strong>Revision History</strong></td>
<td>HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting</td>
</tr>
</tbody>
</table>

HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.
Brief Project Description

A more comprehensive understanding of the risks inherent in the human application sector is crucial to being able to target our resources effectively and ensure that our approach remains risk based and proportionate and that non-compliance is identified and dealt with appropriately.

This project will consider ways in which we can target our regulatory approach in the HA sector, on the basis of risk to both public safety and to public confidence, through addressing the following questions:

- could a more tailored approach be taken to inspections taken into account the two-yearly inspection cycle?
- can our existing approaches be better applied to mitigate risk?
- are there other approaches or tools we could be using to mitigate risk?

The project will be structured into five interdependent work packages that will each run across three project phases:

**Phase 1:** Research – compiling data on the human application sector, identifying areas of risk and researching potential options to mitigate risk (predominantly WP1).

**Phase 2:** Evaluating outcome of possible changes (predominantly WP2,3 &4)

**Phase 3:** Consolidation and delivery (Predominantly WP5)

Individual work package descriptions are set out as separate documents.
The outcome of the project will be proposals to support potential future delivery models aimed at risk-based regulation of the human application sector. The will be delivered as recommendations to the Authority at the start of Quarter 3.

Project administration
Project documentation location
Impact\Programme Office\Projects\In Progress\HA risk

Guidance:
Usually this is >>IMPACT \ Programme Office \ Projects \ Project Name
If a folder has not yet been created you will need to ask IT to create one for you.

Project team
Head of Regulatory Development
Regulation Manager (Policy)
Regulation Manager (Development)
Regulation Manager x 2 (Human Application Team)
Fees and Development Manager (tbc)
Communications and Development Officer
Head of Business Technology – end of Phase 2/Phase 3

Guidance:
List the members of the project team along with their roles.
Usually this will include the sponsor, the Project Manager and any work package owners.
Note: The same person should not have more than one role.

Project Board
DoR/DoPoSC
HoR HA

Guidance:
Reporting expectations on this work package (e.g. weekly meetings)

Reporting arrangements
Project Meetings – Weekly
HTAMG – Monthly
Project board meeting – one per phase (every two months)
Authority Meetings scoping (June 2017) & Delivery
Authority away day – final delivery

Lessons learned review
Areas of focus were identified through licensing and inspection review. Two key areas of difficulty encountered in this project were:

- maintaining an appropriate scope relative to the scale of the project
- dedicating sufficient resource to following through the work.

Another previous piece of work aligned with this one was a paper on joint working with the MHRA. This was completed in 2014 as a standalone piece of work rather than being managed as a project. Consequences of this were:
• not all relevant staff were aware of the recommendations arising from the project.

Adoption of the key recommendations did not happen in a time bound and specific manner

Project tolerances

**Time tolerances**
As this is a six-month project, there is minimal scope for deviation from the milestones set out below. Furthermore, resource is dependent on operational delivery and the implementation of the coding and import Directives. Project milestones and resource allocation will be monitored via weekly project meetings and the scope and deliverables reviewed monthly.

**Financial tolerances**
The project intends to work with existing resources wherever possible. It will use existing data (such as legal knowledge database). If an area is identified that would benefit from supplementary resource (e.g., legal advice, market research) then a case will be presented for approval to SMT.

**Regulatory tolerances**
As this project is considering areas of risk in the HA sector, there is potential that it may identify an area of current practice that is not in line with our regulatory framework, or that sits outside of it completely. There may be scope for addressing these areas through the project outcomes, but this will be decided on the basis of risk. In cases of a clear regulatory breach, this will be escalated through our standard regulatory channels.

Problem handling and escalation

- Regulatory breaches – escalate to DoR via HA HoR and alert Project Board
- Diverting from scope – PM to address through project team meetings
- Resource issues – PM to escalate to project board/sponsor
- Lack of engagement – review root cause at project team meeting and consider review of engagement strategy. If necessary consider escalation through HoR/SMT.

Guidance:
- How should the project manager handle problems?
- Who should be alerted to any problems?

Project Risks

<table>
<thead>
<tr>
<th>Risks &amp; Consequences</th>
<th>Mitigation</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project identifies a regulatory breach by a licensed or unlicensed establishment</td>
<td>Issue to be escalated through the HA HoR and dealt with through our standard regulatory channels.</td>
<td>An uncertain event or set of events that, should it occur, will have an effect on the achievement of objectives.</td>
</tr>
</tbody>
</table>
Linked with above, project identifies a significant risk to patient safety and or public confidence that needs immediate corrective action

Project deters from scope and does not meet milestones

Planning stage has identified issues that may be aligned with this project but that will not be considered within scope. These will be logged separately and resource allocated as needed outside of the project. Project issues log to identify whether issue is in scope or out of scope and will then assign to an owner accordingly.

Insufficient resource to complete the project due to other regulation activities which need to take priority

Project team to report through weekly project meetings and resource allocation monitored depending on other workload of team members.

Lack of buy-in to recommendations from HTA staff and authority members

Ongoing engagement throughout the project will allow staff to be consulted and kept up to date with findings. This will include direct consultation with the HA Team as well as wider consultation through Directorate, all staff and Authority meetings.

Guidance:
Include any risks raised by this project as well as mitigating actions. Risks should be kept updated as necessary and before each new stage begins.

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<table>
<thead>
<tr>
<th>Project structure and progress</th>
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<tbody>
<tr>
<td><strong>Stages</strong></td>
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<tr>
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<tr>
<td>Phase 1 - Research&lt;br&gt;Compiling data on the human application sector, identifying areas of risk and researching potential options to mitigate risk.</td>
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<tr>
<td>Phase 2 – evaluating outcome of possible changes</td>
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<tr>
<td>Phase 3 – consolidation and delivery</td>
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| Project milestones and key tasks |

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<table>
<thead>
<tr>
<th>Date</th>
<th>Milestone / task</th>
<th>Owner</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>31/5/2017</td>
<td>Detailed project plan</td>
<td></td>
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<tr>
<td>12/06/2017</td>
<td>All Staff Away Day</td>
<td></td>
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<tr>
<td>19/6/2017</td>
<td>Regulation Directorate Meeting</td>
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<tr>
<td>27/6/2017</td>
<td>Authority open meeting</td>
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<tr>
<td>31/7/2017</td>
<td>Completion of Phase I</td>
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<tr>
<td>August 2017</td>
<td>Review Paper and presentation on risk</td>
<td></td>
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<tr>
<td>August 2017</td>
<td>Proposals for deployment of resource</td>
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<tr>
<td>31/08/2017</td>
<td>Completion of Phase II</td>
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<tr>
<td>September 2017</td>
<td>Authority Meeting</td>
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<tr>
<td>October 2017</td>
<td>Authority Strategy Away Day</td>
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</table>

### Meeting, action & exception log

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
<th>Owner</th>
<th>Status</th>
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