Eighty-third Meeting of the Human Tissue Authority

Date 8 February 2018  
Time 10 30 – 16 00  
Venue Viceroy Suite, Grosvenor Hotel  
101 Buckingham Palace Road, London, SW1W 0SJ

Agenda

1. Welcome and apologies
2. Declarations of interest Oral
3. Minutes of 9 November 2017 HTA (01/18)
4. Matters arising from 9 November 2017 Oral

Regular Reporting

5. Chair’s Report Oral
6. Chief Executive’s Report HTA (02/18)
7. Delivery Report – Quarter Three 2017/18 HTA (03/18)
9. Deployment Report – Quarter Three 2017/18 HTA (05/18)
10. White space for non-agenda items Oral
   • Discussion on media interest
   • Global Kidney Exchange

Committee and Advisory Group Reporting

11. ARAC update – 1 February meeting Oral
12. Histopathology Working Group Meeting Oral

Policy Issues

13. Regulatory Futures HTA (06/18)
14. HTA Strategy 2018 – 2021 HTA (07/18)
15. Shared Directorate Review HTA (08/18)

Other Items

16. Any other business Oral

Confidential session

17. Confidential items

Afternoon Session

14 30 – 16 00  Lisa Burnapp, Lead Nurse – Living Organ Donation, NHSBT
### Minutes of the Eighty-second meeting of the Human Tissue Authority

**Date** 9 November 2017  
**Venue** Viceroy Suite, Grosvenor Hotel  
101 Buckingham Palace Road, SW1W 0SJ

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<th><strong>Present</strong></th>
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<tr>
<td><strong>Members</strong></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>Dr. Hazel Lofty (Interim Director of Policy, Strategy and Communications)</td>
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<td>Dr. Stuart Dollow</td>
<td>Richard Sydee (Director of Resources)</td>
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<td>Amanda Gibbon</td>
<td>Kevin Wellard (Quality and Corporate Governance Manager)</td>
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<td>Prof. Andrew (Andy) Hall</td>
<td>Jessica Porter (Head of Regulation)</td>
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<tr>
<td>William (Bill) Horne</td>
<td>Morounke Akingbola (Head of Finance and Governance)</td>
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<tr>
<td>Glenn Houston</td>
<td>Dr. Christopher Birkett (Head of Regulation) (Item 10)</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>Prof. Anthony Warrens</td>
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<td>Prof. Penney Lewis</td>
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<td>Dr. Lorna Williamson, OBE</td>
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| **Apologies** |                     |
| Sarah Bedwell (Director of Regulation) |                     |

<p>| <strong>Observers</strong> |                     |
| Jeremy Mean (Department of Health) |                     |</p>
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<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
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| **Item 1** | Welcome and apologies | 1. The Chair welcomed Members, attendees and observers to the eighty-second meeting of the Human Tissue Authority.  
2. The Chair noted that Jeremy Mean from the Department of Health (DH) would observe the meeting.  
3. An apology for absence had been received from Sarah Bedwell (Director of Regulation). |
| **Item 2** | Declarations of interest – Oral | 4. The Chair asked Members if they had any personal or pecuniary interests to declare in relation to items on the meeting’s agenda.  
5. Members disclosed the following interests:  
   a. Prof. Penney Lewis – Member, Children and Young People’s Advisory Committee, Genomics England  
   b. Bill Horne – In a previous role, oversaw investigations, where tissue would have been recovered and retained at the Mortuary of University Hospital Wales although he was not aware that any of those investigations were related to the failures in the recent inspection.  
   c. Prof. Andy Hall – NHS Research Ethics Committee, (Newcastle and North Tyneside 2) |
| **Item 3** | Minutes of 14 September 2017 Authority meeting – HTA (36/17) | 6. The Chair asked if the minutes represented an accurate record of the 14 September 2017 meeting.  
7. The minutes were accepted as an accurate record of the meeting, subject to the minor redrafting of paragraph 65. |
| **Item 4** | Matters arising from 14 September 2017 Authority meeting – Oral | 8. The Chair confirmed that copies of the business continuity and
out of hours’ assessment process for living donor transplant cases had been circulated prior to the meeting regarding Action One (Recirculate the out of hours’ guidance to Members).

9. Allan Marriott Smith advised Authority Members that an initial update on Action Three (Review and report to Members about non-positive feedback received from the annual conference networking and drop-in sessions) had been included in the Chief Executive Report, under item six of the agenda. Members were advised that this item would remain an ongoing action to enable a further update on this issue at the 8 February 2018 Authority meeting.

10. The Chair advised members that Action Six (Contact the Bishop of Carlisle regarding the potential for the Hospital Chaplains’ Council to volunteer as Independent Assessors) had been superseded as an action within the ongoing project to review the Sustainability of the Independent Assessor Framework.

11. Authority Members were advised that Action Three (Review the use of private telephone numbers as part of the enquiries project) would be reviewed by Jessica Porter, who would then provide members with an update at the 8 February 2018 Authority meeting.

12. Members asked for assurance from the SMT regarding its mitigation of the information security risks relating to the HTA’s Customer Relationship Management (CRM) system that were identified during a DH data audit. Allan Marriott-Smith assured members that these risks would be addressed via a combination of existing cyber security updates and the planned CRM upgrade. This issue would also continue to be reviewed at the HTA Management Group (HTAMG), the Audit and Risk Assurance Committee (ARAC) and by Members via the Quarterly Reporting to the Authority. Members were assured that they would also receive further information prior to the CRM upgrade.

13. The Chair noted that all other actions from the 14 September 2017 meeting were resolved, ongoing in nature, or would be addressed during the meeting.
14. Item 10 – White space for non-agenda items. Members were advised that they would have an opportunity to discuss the key issues arising from the ‘US Body Trade’ article that was recently published by the Reuters News agency.

15. The Chair asked Members for any further matters arising; none were raised.

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<td>16.</td>
<td>The Chair asked Authority Members to note the final iteration of the Members’ performance objectives for 2017/18, which had been circulated prior to the meeting.</td>
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<td>17.</td>
<td>The Chair tabled a paper revising Authority Members’ membership of advisory groups and committees. The purpose of the paper had been to set out the principles applied in the allocation of individual Members to specific groups. The Chair invited comments on the proposals but no material concerns were raised. Members agreed to the recommendations within the paper.</td>
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<td>18.</td>
<td>Jeremy Mean provided an update on the recruitment of the HTA’s new Chair. Members were advised of a slight delay in advertising the role, but were assured that a new Chair will be appointed early in the new year. Members were advised however that this was dependent on the notice requirements of the appointed candidate. Members were further assured that should there be a delay in a new Chair taking up the role, Sharmila Nebhrajani has agreed, if necessary to remain Chair until the new Chair takes up post.</td>
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<td>19.</td>
<td>Members of the Authority asked if the Chair was permitted to designate an existing Member to operate as an interim replacement, until a new Chair is appointed to take up the role. Members also suggested the appointment of a Deputy Chair, as an alternative option to address the current situation and for any future occasions when the Chair is absent. Allan Marriott-Smith advised Members that there was existing provision within the Authority’s standing orders for the appointment of an existing lay Member to chair Authority meetings.</td>
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<td>20.</td>
<td>The Authority agreed that Sharmila Nebhrajani, Allan Marriott-Smith and Jeremy Mean should consider the proposals to</td>
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appoint an interim and/or Deputy Chair and provide members with an update in advance of the February Authority meeting.

21. The Chair invited Members to submit any further comments or suggestions to her or Allan Marriott-Smith for further consideration.

**Action One:** The Chair, Allan Marriott-Smith and Jeremy Mean should consider the proposals to designate an interim and/or Deputy Chair and provide members with an update.

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<th>Chief Executive’s Report – HTA (37/17)</th>
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<tr>
<td>22.</td>
<td>Allan Marriott-Smith presented this item and introduced the report.</td>
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<td>23.</td>
<td>Alan Marriott-Smith and Richard Sydee assured members that the Strategic Risk Register had been revised to correct the discrepancy between the risk ratings contained within the detailed risk assessments for individual risks and the summary risk ratings on the front page of the register that had been identified at the last ARAC meeting.</td>
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<td>24.</td>
<td>Richard Sydee advised Members that he had investigated this matter and that previously the SMT had accurately entered its assessment of headline risks without recourse to the underlying risk formulas that were built into the detailed elements of the register. Members were advised that this issue had been corrected and that an updated register had been included within the meeting packs for this meeting.</td>
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<td>25.</td>
<td>Bill Horne asked other Authority Members to note that the HTA’s governance arrangements for risk management had recently received moderate assurance from Internal Auditors.</td>
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<td>26.</td>
<td>Allan Marriott-Smith advised that four of the five strategic risks (found in <strong>Annex A</strong>) were assessed to be stable as of October 2017. In October, SMT had identified upward pressure in risk 4 – <em>Failure to utilise our capabilities effectively</em>, although the residual risk assessment remained amber. This was to reflect the recent departure/resignation of two members of the SMT and the associated risks to corporate knowledge and to management and leadership capability within the organisation.</td>
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27. Members were advised that the SMT would also, as a matter of priority, be considering the opportunity to balance the budget for the current financial year which could be achieved by leaving posts vacant. This decision would be balanced against the need to maintain operational capability.

28. Allan Marriott-Smith advised the Authority that SMT had taken an active decision to reduce the number of inspections scheduled during quarter four of the current business year to 29 to allow resource to be dedicated to a number of pressing development priorities. The target number of site visits for the year would still be met. Allan Marriott-Smith advised the Authority that the HTA Management Group would be mapping out the specific resource requirements of individual projects at its meeting on 16 November.

29. Jeremy Mean informed the meeting that during December, the Department of Health (DH) would commence consultation on the introduction of opt-out legislation for deceased organ donation in England. Separately, a Private Members’ Bill the “Organ Donation Consent Bill 2017-2019” is also being prepared for publication with the second reading of the Bill scheduled for 23 February 2018.

30. Members were advised that NHSBT would be consulted during this period. Members suggested that DH might also engage the British Transplantation Society Ethics Committee and former members the UK Donation Ethics Committee during the consultation period. In view of the limited time available, it was suggested that the latter could be convened on a ‘virtual’ basis. Members also advised that the DH should specifically seek to engage representative faith based groups within the consultation process.

31. Jeremy Mean advised the he would consider the suggestions raised by Members as possible options to be included within the consultation arrangements.

32. HTA Executive agreed to provide Authority Members with a copy of the minutes arising from the quarterly DH/HTA accountability meeting.

33. The Authority noted the remaining content of this report.
**Action Two:** The HTA Executive to routinely provide Authority Members with a copy of the minutes arising from the quarterly DH/HTA accountability meeting.

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<tr>
<td>34.</td>
<td>Hazel Lofty presented this item and introduced the report.</td>
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<td>35.</td>
<td>Members were advised that the HTA had found three critical shortfalls in two Post Mortem sector establishments that have been inspected during quarter two. The report of the inspection of one of these establishments had been published prior to the meeting and attracted some media attention. Similar shortfalls had been discovered at that establishment on previous inspection in 2009. Members were assured that the HTA had been proactively working with the establishment to resolve the issues identified and to ensure effective communication surrounding the publication of the report.</td>
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<tr>
<td>36.</td>
<td>Members were also assured that the HTA had been proactively working with the police, Home Office, the Welsh Government and Health Inspectorate Wales (HIW). Further site visits are anticipated in order to ensure that the shortfalls and other emerging issues are appropriately addressed. It was agreed that the HTA should work proactively with the Histopathology Working Group (HWG) and Royal College of Pathologists (RCPath) to maintain the HTA’s constructive relationship with the sector.</td>
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<td>37.</td>
<td>Hazel Lofty advised the Authority, that the HTA had conducted two non-routine inspections of Post Mortem establishments during quarter two. One had arisen in response to an incident that resulted in the closure of a mortuary for five months. The other inspection had been instigated in response to concerns raised by a funeral director concerning the dignity of the deceased and care of bodies being released to them.</td>
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| 38.    | Members were assured however, that the first of these establishments had been assessed as being suitable to be licensed subject to the implementation of corrective and preventative actions. Members were also assured that the second establishment had been found to be compliant with the HTA’s Standards with no evidence discovered to substantiate
the funeral director’s concerns.

39. Hazel Lofty drew the Authority’s attention to the emergent increase in the number of shortfalls and associated regulatory pressures arising from the inspection of post mortem establishments. These shortfalls had primarily arisen in relation to standards of governance and the maintenance of premises, facilities and equipment. Members were advised that seven critical shortfalls had been identified in the current financial year compared to just one in the previous five years. Work will be undertaken to interrogate the HTA’s data on inspections, HTA Reportable Incidents (HTARIs) and shortfalls, to identify the root causes of this trend.

40. Members of the Authority enquired about the HTA’s capacity to augment the HTA’s regulatory establishment with freelance staff drawn from people previously employed as Regulation Managers. Allan Marriott-Smith advised members that this was an option but would be subject to further investigation.

41. Members of the Authority queried the increased trend toward lone working within mortuaries and the increasing prevalence of accidental damage to bodies reported in table two: HTARIs in the post mortem sector, within the report. Members also queried the relatively large proportion of incidents that are recorded under the ‘any other incident’ category within the table and requested greater precision in the specific detailing of categories for future reports.

42. Jessica Porter advised the Authority of the possibility that shortfalls concerning the maintenance and condition of facilities, premises and equipment could be related to underlying funding issues and that many establishments welcome inspection findings as a lever to drive improvements.

43. Members discussed the need to publish the continuous learning arising from inspections and HTARIs; the possibility of leveraging peer-to-peer support across establishments; and the need to advise NHS England of the risks and issues arising within the sector. Members also suggested that the criteria for non-routine inspections could be circulated to funeral directors in order to better inform the reporting of concerns.
| 44. | Members asked for clarification on the licensing requirements for body stores. Hazel Lofty advised that, under the Human Tissue Act, the licensing of premises was dependent upon the scheduled purposes they were undertaking and agreed to provide Members with a more detailed written response on this issue. |
| 45. | Hazel Lofty advised the Authority that an investigation had been conducted into the procurement of adipose tissue by two licensed establishments and the export / import to / from a European Institute. Appropriate authorisation and licences were not in place for this work prior to the activities being undertaken. The MHRA was contacted about the issue and it is investigating the matter separately. |
| 46. | Hazel Lofty advised that the HTA’s investigation had concluded and that it was agreed at the Regulatory Decision Meeting held on 27 July 2017, that a breach of the tissues and cells legislation had been committed by both parties. After careful consideration however, the SMT had decided that the matter did not warrant referral to the police for investigation. |
| 47. | Members were provided with an update on a police referral previously identified in the 2016/17 quarter four Delivery Report. Members were reminded that a European Union (EU) Competent Authority in another Member State had made the HTA aware of a website, which appeared to offer a British matching donor service in exchange for a fee (for deceased donation). |
| 48. | This issue was referred to the police who in turn had referred the matter on to the Competent Authority country in which the company offering the service is registered. Members were assured that the matter remained under investigation and the HTA was continuing to liaise with colleagues in the relevant Member State. In August 2017, the HTA released a position statement, which issued a warning to members of the public to exercise caution when registering to become an organ donor with services other than the NHS Organ Donor Register. This received some limited press coverage. |
| 49. | Members asked for clarification on a living donor organ transplant, which had proceeded without the HTA’s approval. |
50. Members counselled the Executive to communicate the seriousness of this incident to the establishment. Members also asked for assurance on the robustness of the reporting and decision-making processes on the notification of such incidents and stressed the importance of governance at the establishment by the Designated Individual (DI).

51. The Authority was advised that the HTA was awaiting the root cause analysis report from the establishment concerned, before it would decide what action was necessary. Members were assured that they would receive an update on this issue at the 8 February 2018 Authority meeting.

52. Members noted that the ‘open rate’ for the Independent Assessor bulletin was relatively lower than the open rate for the public newsletter. Members were assured that managers would continue to monitor and evaluate the effectiveness of the HTA’s external publications.

53. Members asked for an update on the HTA’s proposed regulatory response to the prospect of the UK’s first human taphonomy facility. Allan Marriott-Smith advised the Authority that the HTA’s regulatory response to this issue was currently on hold subject to further liaison with the parties involved. Members will receive an update on this issue at the 8 February 2018 Authority meeting.

54. The Authority noted the remaining content of this paper.

**Action Three:** Dr. Lorna Williamson to raise the issues arising from the inspection of establishments and critical shortfalls arising within the Post Mortem Sector, with the Royal College of Pathologists.

**Action Four:** Hazel Lofty agreed to include agenda items for the Histopathology Working Group meeting on the issues arising from the inspection of establishments and critical shortfalls arising within the Post Mortem Sector.

**Action Five:** Managers to itemise the ‘any other incident’ category within table 2: HTARIs in the post mortem sector into more precise categories in future quarterly delivery reports.
Action Six: Hazel Lofty to provide Authority Members with a written response on the licensing of body stores under the Human Tissue Act.

Action Seven: at 8 February 2018 Authority meeting, Members to receive an update on the HTA’s response to the living donor organ transplant which had proceeded without HTA approval.

Action Eight: Members to receive an update on the HTA’s proposed regulatory response to the prospect of the UK’s first human taphonomy facility at the 8 February 2018 Authority meeting.

Item 8 Development Report – Quarter Two – HTA (39/17)

55. Hazel Lofty presented this item and introduced the report.

56. Hazel Lofty advised the Authority that progress on implementing the European Union (EU) Coding and Import Directives had remained limited during quarter two. The Authority was advised that the HTA was awaiting further communication from the DH regarding Ministerial approval for the transposition. Members were assured that the pause to this project had enabled the executive to focus on progressing other development work but were advised that uncertainty about the timing of the transposition would continue to pose a risk to the HTA as significant resources would likely need to be reallocated at short notice to implement the Regulations by the coming into force date.

57. Jeremy Mean provided an oral update on this issue. Members were advised that the Regulations were expected to be laid in Parliament during November/December. The Regulations were due be debated by Parliament early in 2018 and were expected to come into force on 1 April 2018.

58. Hazel Lofty assured the Authority that once confirmation of ministerial approval had been received, the HTA would provide further advice for licensed establishments on the likely timetable and the process for re-issuing import licences.

59. Hazel Lofty thanked Amanda Gibbon and Dr. Stuart Dollow for
their participation in the project to evaluate risk in the human application (HA) sector. Authority Members were advised that each of three phases of this project: considering inspections; preparation process dossiers; and third party agreements had now been completed.

60. Hazel Lofty assured the Authority that the findings of each of the work packages have been consolidated into a series of recommendations for the future regulation of the HA sector. Members were also assured that all of the strategic recommendations had been incorporated into the HTA Strategic Review. Members were advised however, that the recommendations had yet to be formally approved by the project board or the SMT and that delivering the recommendations would be subject to the allocation of resources.

61. Hazel Lofty advised Members that the analysis had been completed on the first tranche of data to inform the Authority report on safety within the HTA regulated sectors. It was agreed that Members would receive the completed report at its public meeting in June/July 2018.

62. Hazel Lofty updated the Authority on the progress of the licensed establishment relationship programme. Members were advised that new web content had been developed dedicated for use by DIs from licensed establishments. Positive feedback has also been received from stakeholders on the improved search functionality for inspection reports, which allows users to see the latest reports for each sector.

63. Members were advised that the next phase of the programme would see the development of online tests on the three main pieces of HTA legislation (HT Act, Q&S Regulations and ODT Regulations). Draft questions for the tests had been developed but would be reviewed by the Regulation Directorate before they were launched. Members were informed however, that progress on this project had been delayed due to a staff resource limitations, but would be prioritised for completion during Q3.

64. Chris Birkett gave Authority Members an update on the biennial collection of compliance data from licensed establishments.
Members were advised that the collection of these updates would continue to guide the HTA’s regulatory approach to each sector and would inform the ongoing scheduling of site-visit inspections. Members were assured that the collation process had been completed and that the data would now be circulated to individual sector teams for analysis.

65. The Authority noted the content of this paper.

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<td>66.</td>
<td>Allan Marriott-Smith and Richard Sydee presented this item. Allan Marriott-Smith introduced the report and updated the Authority on human resource issues at the HTA. Members were advised that following a recent period of stability, the staff attrition rate had reduced below the 18% target during quarter two. However, the Authority was advised that two experienced staff had departed from the HTA and that further departures were due to occur during quarter three.</td>
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<td>67.</td>
<td>Members were informed that an internal candidate had recently been appointed as a Regulation Manager (RM) but that the recruitment of a RM for the Human Application Team had not been successful. Allan Marriott-Smith advised Members that the HTA would be reviewing its approach to the recruitment of RMs, during quarter four including drawing from a wider geographic pool.</td>
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<td>68.</td>
<td>Richard Sydee provided the Authority with an update on the HTA’s financial position for the end of quarter two. At its meeting in October, the SMT agreed a forecast year-end position for a deficit in the region of £44k. This position took into account potential ongoing budget savings; the additional inspection costs accrued during the first three quarters of the year; additional, unforeseen recruitment costs; and where necessary but appropriate, not filling other vacancies.</td>
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<td>69.</td>
<td>Richard Sydee advised the Authority that the DH had yet to confirm that it would meet the additional office rental costs incurred by the HTA. Members were advised that the HTA was expecting the DH to confirm its position on this issue by January 2018.</td>
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<td>70.</td>
<td>The Authority was advised on the 30 September 2017, the</td>
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HTA’s licence fee debtor balance was £1,975k. Richard Sydee assured the Authority that whilst this represents an increase in comparison with last year (£1,881k in the same period 2016/17), he was not unduly concerned at this early stage in the cycle of debt collection.

71. The Authority agreed the revised budget forecast for the remainder of the 2017/18 financial year.

72. Richard Sydee also advised the Authority that assessment had been conducted to ascertain the complexity and effort required to complete the CRM upgrade. The assessment did not uncover any major obstacles but did confirm that the majority of the HTA’s custom code would need to be rewritten.

73. The Authority noted the remaining content of this paper.

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

74. Allan Marriott-Smith introduced this item and invited Members to discuss the key issues and considerations for the HTA arising from the ‘Body trade’ articles, recently published by the Reuters News agency. Chris Birkett provided the Authority with an overview of the HTA’s remit regarding this issue.

75. Members were advised that it is common practice for UK establishments licensed by the HTA to import bodily materials from providers based in the United States of America (US) for anatomical or surgical teaching (although the import itself is not licensable). Members were informed however, that the HTA does not collate figures on the import of body parts. Members were further advised that these establishments were likely to import from the larger and more reputable US suppliers.

76. Chris Birkett reflected that it is well understood that all bodies and body parts should be treated with respect and dignity. There are also potential health and safety risks associated with fresh frozen cadaveric material. Our experience of regulating anatomy sector establishments in the UK is that there is a strong ethos of responsible and ethical custodianship; for example, it is a common experience for us to hear of establishments undertaking assurance visits of their suppliers.
77. Chris Birkett advised members that the consent provisions of the Human Tissue Act 2004 (the Act) do not apply to material donated within the US. Members were reminded that, under the Act, establishments do not require a licence to import bodies or material but do require a licence for the storage of bodies or material for purposes set out in the Act.

78. Members were assured that the HTA’s anatomy code of practice contains recommendations about consent assurances and provides further expectations with respect to ethical responsibilities. We also give consideration to potential health and safety risks, and how these can be managed. Consent and traceability are also covered by HTA’s licensing standards. We also provide a general policy on the sale of bodies, body parts and tissue on our website. We review supply arrangements, and may audit linked documentation, during our inspections.

79. Members queried the demand for imported body parts, particularly as there is a commonly held perception that anatomical establishments in the UK often reject local offers of whole body donations. Chris Birkett advised members that the demand for imported material is likely to reflect the specific requirements of importing establishments; for example, they may need a certain number of specific parts in order to provide tailored surgical training – this is a separate demand to that for the whole bodies required for conventional anatomy teaching.

80. Chris Birkett informed members that he had discussed the media coverage with our Head of Communications and agreed that an article would be included in the next stakeholder newsletter. This seemed a timely opportunity to reinforce our recommendations and expectations with regard to imported material.

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<td>81.</td>
<td>Amanda Gibbon – Chair of the ARAC, provided Authority Members with an overview of the items of business discussed and matters arising from the 2 November ARAC meeting.</td>
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<td>82.</td>
<td>Amanda Gibbon advised the Authority that the committee had received an explanatory briefing from the DH ‘Brexit’ specialist Neel Naik, setting out the timetable and process for the UK’s</td>
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Members were advised that the committee had agreed to provide the DH with a briefing paper on the implications of the UK leaving the EU on the pan-European regulation of human tissue and organs. Members were assured that the Authority would receive a draft of the briefing paper for review at the 8 February 2018 Authority meeting.

83. The Authority were advised that the ARAC had agreed to the SMT conducting a review of the committee’s audit recommendations tracker against the organisation’s ongoing resource priorities. Members were also assured that the committee had agreed the final iteration of HTA 2017/18 internal and external audit assurance plans. The Committee had also received moderate assurance from auditors on the HTA’s risk management governance arrangements and had explored the issues and recommendations arising from the recent project to evaluate risk in the human application sector.

**Action Nine: Members to receive a briefing note on the Regulatory implications for human tissue and organs of the UK Exiting the EU.**

### Item 12 Stakeholder and Fees Group update – HTA (41/17)

84. Bill Horne referred members this report setting out the matters arising from the Stakeholder and Fees Group, which had been held on 18 October 2017.

85. Members noted the content of the report.

### Item 13 Transplant Advisory Group update – (Oral)

86. Jessica Porter provided a brief update on the matters arising from the Transplant Advisory Group (TAG) meeting, which had been held on 18 October 2017. Key discussions had focussed on the policy changes that took place earlier in the year and the plans for the project on sustainability of the Independent Assessor framework and Independent Assessor reaccreditation process.

### Item 14 Licence fees – HTA (42/17)

87. Richard Sydee presented this paper, setting out the recommended budget to be recovered from fees during 2018/19. Members were advised that the revised budget had
incorporated previously deferred costs from 2017/18 and reflected increasing cost pressures, in particular accommodation costs. SMT recommended that fees should be set to recover £3.7m.

88. The fees proposal had been discussed by the Stakeholder and Fees Group on 18 October. Members were advised that the group had not been wholly in favour of the proposed increases but had recognised that the current HTA budget was not sustainable. The Group was concerned however, that the HTA continue to keep its costs down to avoid further financial burden to establishments.

89. Richard Sydee advised the Authority that the longer-term fee levels would need to account for the ongoing decline in the number of licensed establishments. The Authority were advised to consider the need for a strategic review of the current fees structure to address this issue.

90. The Authority acknowledged the reasonable case for an increase in fees but discussed the need for a clear and robust communications campaign to explain the HTA’s position more widely to licensed establishments.

Action Ten: the SMT agreed to devise a clear and robust communication campaign to coincide with the publication of the HTAs 2018/19 licence fees.

Item 13  Confidential minutes of 14 September 2017 – HTA (C35/17)
91. Jeremy Mean left the meeting for this item.

92. The Chair reminded Members that this extra session of the Authority meeting was confidential to Members. This item was taken in closed session immediately after the non-confidential items on the agenda.

93. The Chair asked Members if the minutes were an accurate record of the confidential session held at the 14 September 2017 Authority meeting. The minutes were accepted as an accurate record of the session, subject to the amendment of paragraph 14.

94. The Chair asked members if there were any matters arising
from the confidential session held at the 14 September 2017 Authority meeting; none were raised.

<table>
<thead>
<tr>
<th>Item 14</th>
<th>Any Other Business – Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>95.</td>
<td>Sharmila Nebhrajani, thanked the members and staff attendees for their help, support and contributions to the Authority’s business during her time as the HTA Chair. The Members of the Authority congratulated the Chair on her new appointment and for her achievements as the Chair of the HTA. Members also thanked the Chair for her service to the Authority.</td>
</tr>
</tbody>
</table>

The meeting closed at 12:38
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 during November 2017 to January 2018, which are not reported elsewhere.

Decision-making to date

2. This report was approved for submission to the Authority by the Chief Executive on 25 January 2018.

Action required

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

Overview of strategic risks

4. Four of the five strategic risks (found in Annex A) were assessed to be stable as of January 2018. In January, SMT identified downward pressure on risk 5 – Insufficient, or ineffective management of financial resources, with the residual risk assessment remaining yellow. This is to reflect the small surplus that is now forecast after the Quarter three review.

5. The Regulations required to implement the EU Coding and Import Directive were laid before Parliament in December 2017, with a debate due early in the New Year. The
coming into force date will be 1 April 2018, and significant resource will need to be deployed to implement the requirements. A more detailed update will be provided as part of the Development report.

Other issues

Development of the HTA Strategy 2018 to 2021

6. The Authority reviewed the Strategy proposal document at its annual away day on 19 October, and provided very useful advice on the strategic direction for the HTA over the three years from 2018/19.

7. This advice has been used to produce a draft of the Strategy, which will be discussed at agenda item 14.

8. Work on the blueprint for the future operating model will begin late in quarter four and into the 2018/19 business year, with careful consideration given to balancing current and emerging priorities during the first year of the new Strategy period.

Organ donation opt-out in England

9. As anticipated, the Department of Health and Social Care (DHSC) launched its consultation on a new opt-out system for organ donation for England in December 2017. The consultation will run for three months and will close at midnight on 6 March 2018.

10. It is remains unclear what, if any, role would be required of the HTA under any legislation that the government may ultimately bring forward.

11. Our draft response to the consultation is included at agenda item 18 for Members’ views. The response draws on our experience of producing the Code of Practice for professionals working under the Human Transplantation (Wales) Act 2013 that created the opt-out system of organ and tissue donation for adults who live and die in Wales.

Northern Ireland Consultation on Organ Donation

12. In December 2017, the Department of Health in Northern Ireland launched a public consultation to help inform the Department’s future approach to promoting organ donation in Northern Ireland, with a view to increasing the number of successful organ and tissue donations. The policy proposal sets out a series of commitments centred on coordinated engagement and education activities in order to fulfil the statutory requirement introduced by the Assembly in 2016, requiring the Department of Health to promote organ donation.
13. Our intention is to submit a response to the consultation, in broad support of the Department’s proposals and emphasising the importance of valid and informed consent.

Human Taphonomy

14. As Members will recall, the HTA has been asked to provide advice on the establishment of a Human Taphonomy Centre in the United Kingdom. An update on the latest position will be provided orally at the meeting.

Cryopreservation

15. Members will recall that further work on cryopreservation was postponed until later in the business year due to resource constraints and other priorities. In line with previous Authority discussions, the HTA intends to publish light-touch guidance for the public and licensed establishments early in the new business year. The public-facing guidance will be informed by feedback from the HTA’s public panel.

Licensing of body stores

16. At the previous meeting, Members asked for further information on body storage facilities, which are not covered by a licence.

17. The licensing requirement of the HT Act for storage of bodies only applies to ‘storage of the body of a deceased person for use for a scheduled purpose’ (e.g. determining the cause of death). As such, the licensing requirements do not apply to establishments who are only storing bodies prior to release for burial or cremation. Hospitals may therefore operate body storage facilities, which are not licensed by the HTA. Similarly, our licensing requirements do not extend to funeral directors.

Health Select Committee Response

18. The HTA has submitted written evidence to the House of Commons Health Committee inquiry on ‘Brexit – medicines, medical devices and substances of human origin’. Our evidence focussed on our role as the Competent Authority for tissues and cells, and organs, and highlighted areas of regulation that may potentially be impacted by the UK’s exit from the EU.

19. Members will have an opportunity to discuss this further as part of the paper on EU exit at agenda item 17.
Cosmetic Product Regulation

20. The HTA contributed to a DHSC submission for Ministers on a range of policy options to meet the Conservative manifesto commitment to “ensure there is effective registration and regulation of those performing cosmetic interventions” which may have an impact on our regulation in the Human Application sector.

21. Key areas we highlighted included classification of borderline products; clinical efficacy for tissue and cell products; and issues relating to the ‘same surgical procedure’ exemption.

22. We will keep Members informed of any further developments.

Advertising Standards Authority (ASA)

23. In November last year, the HTA met with colleagues at the ASA to discuss how the two organisations could work together where there are potential issues around misleading marketing materials being produced by HTA licensed establishments. The discussion focused on approaches to how these issues could be flagged up and handled, and it was agreed that the HTA would share a case study with the ASA to establish what sort of action may be appropriate for any future referrals. This work is ongoing, further discussions will be held with colleagues at the ASA to establish what a future system for identifying, and addressing the potential issues may look like.

Alternatives to burial or cremation

24. Members may be aware of recent press coverage relating to alternatives to burial or cremation for the disposal of human remains. The main drivers appear to be claims that the processes are more environmentally friendly than traditional methods. Both alkaline hydrolysis and freeze drying have featured in recent articles, although neither are entirely new technologies, and there has been discussion around them for a number of years.

25. In mid-December, the Ministry of Justice (MoJ) informed us that the Law Commission’s 13th Programme of Law Reform had been laid in Parliament and includes a project on “A modern framework for disposal of the dead”. The expected duration of the project is 2-3 years.

26. This project will seek to create a future-proof legal framework that brings the existing law into line with modern practices and enables safe and dignified new processes to be made available in England and Wales. The project would also seek to provide greater certainty that a person’s wishes in respect of what happens to their body following death are respected, whilst ensuring that the public interest in this sensitive area of law is properly respected.
27. Although this would not fall directly under our regulatory remit, we will maintain a watching brief and keep Members updated.

Accountability to the Department of Health and Social Care

28. The HTA met with the DHSC on 11 January 2018 as part of its regular accountability meetings. Items on the agenda included:

- Fees for 2018/19
- HTA Accommodation and VAT position
- EU Directives on Import and Coding
- EU Exit and Health Select Committee Inquiry
- Organ donation Deemed Consent Bill (second reading on 23 February 2018) and Government consultation on system of opt-out for organ donation
- 2018/19 Business Planning Process
- New Chair recruitment
- PM sector issues
- Options appraisal on regulation of cosmetic products

29. We also outlined our progress against key performance indicators, our current assessment of strategic risk and the 2017-18 in year financial position.

30. The Department took assurance from the meeting and no significant issues were raised.

31. Minutes of the October accountability meeting have been circulated with the Authority papers for information as requested.

Complaints report

32. The HTA has received two complaints about the organisation in quarter three.

33. The first related to how the HTA had managed its relationship with a licensed establishment and comprised three strands: failure to respond to questions, provision of inconsistent advice, and tone of correspondence. The investigation partially upheld the first of these, but did not uphold the latter two.

34. The second related to alleged failures in management and leadership of the organisation. The Authority met to discuss the content of the complaint and, in line with the HTA complaints policy, decided to take no formal action, as the complaint was anonymous.
Overview: Risks reflect the strategy for 2016-19 (year two update published in April 2017 (2017/20 document)). Our highest risks are now the failure to manage expectations of regulation, which reflects the fast-rate of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively which is currently affected by the fact the Head of Business technology is new to the organisation.

Other notable risks: Final delivery of some 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 other 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>Nov 2017</th>
<th>Dec 2017</th>
<th>Jan 2018</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - Failure to regulate appropriately (Risk to Delivery a-c &amp; d 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 organisation’s capability and strengthened our regulatory regime and recruitment for the one remaining RM vacancy has commenced - the initial response to the advert was disappointing and we have re-issued the advert. We will continue to monitor our ability to attract suitable candidates to HTA positions.</td>
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<tr>
<td>2 - Failure to manage an incident (Delivery, Development and Deployment)</td>
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<td></td>
<td></td>
<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></td>
<td></td>
<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 number of perimeter issues shows no sign of decreasing. The regulations on import and Coding have now been laid before parliament. Although this has relieved the uncertainty we now face a significant exercise to request and assess applications, and issue new import licences that are aligned to the new regulations. We anticipate that to exercise may not be complete by 31 March 2018</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>
<td></td>
<td></td>
<td></td>
<td>We continue to be in a position to use the skills of our newer recruits more fully. A recent departure and a further resignation at the SMT level introduce some risks to corporate knowledge. Management and leadership capability may take some time to rebuild at this level. The likelihood of achieving full compliance with GDPR by 25 May 2018 is currently being assessed; we remain confident that key data holdings and policies will remain compliant with a defensible position with the ICO for achieving full compliances for any outstanding areas post the implementation date.</td>
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<td>5 - Insufficient, or ineffective management of, financial resources (Deployment b)</td>
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<td></td>
<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 although we have received confirmation that DH will meet the costs of the increased rent costs at 151 BPR as they did in 2016/17. Our recent review of forecast expenditure through to the year end, undertaken at the end of quarter 3, has indicated we are headed for a small surplus of c£30k</td>
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Risk scoring matrix

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<thead>
<tr>
<th>Impact</th>
<th>Delivery</th>
<th>Development</th>
<th>Deployment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very High</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>Very High</td>
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<tr>
<td>High</td>
<td>Medium</td>
<td>Very High</td>
<td>High</td>
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</tbody>
</table>

Risks are assessed using the grid below

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
<th>Delivery</th>
<th>Development</th>
<th>Deployment</th>
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<tbody>
<tr>
<td>Very Low</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
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<td>Low</td>
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<td>Medium</td>
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<td>Medium</td>
<td>Medium</td>
<td>High</td>
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<tr>
<td>High</td>
<td>Very Low</td>
<td>Very Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Very High</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
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</tbody>
</table>

Lines of defence:

- Embedded in the business operation
- Corporate oversight functions
- Independent of the HTA

Deployment – to make the most-effective use of our people and resources in pursuit of our goals

- To manage and develop our people in line with the HTA’s People Strategy
- To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- To provide a suitable working environment and effective business technology

HTA (02/18) Annex A
HTA Strategy 2017 to 2020 clearly articulates the HTA's regulatory model

Preventative Authority developed and approved the HTA Strategy

HTA Strategy published on 1 April 2017

Regulatory decision making framework

Preventative Reports to Authority of key decisions in Delivery Report

Satisfactory report made in September 2017

Annual scheduled review of Strategy

Preventative Outputs from annual strategy review translate into revised annual Strategy

Annual strategic planning away day completed in October 2017

Approved HTA Business Plan 2017/18 identifies a balanced programme of regulatory activity and continuous improvement

Preventative/ Monitoring Sign off of the business plan by the Chair on behalf of the Authority and by sponsor Department

HTA Business Plan published on 1 April 2017 and approved by the Department of Health

HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model

Preventative/Monitoring Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates

Management are aware of limitations in the QMS and have further work planned in 2017/18 to address these

Training and development of professional competence

Preventative/ Monitoring Annual PDPs, RM proposals to SMT

Regulation training plan agreed by SMT in June. Training records added onto Simply Personnel and monthly HR updates presented at SMT.

Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas

Preventative/Monitoring SMT assessment of skills requirements and gaps as vacancies occur. Recruitment policy

Staffing levels and risks reported quarterly to the Authority

Internal audit of quality management system adequacy and adherence (HL) by March 2018

Preventative/ Monitoring Staffing levels and risks reported quarterly to the Authority

Delivery of Licensing and inspection review projects to strengthen our regulatory model (HL) by March 2018

Preventative Close the following to be refined when controls in place

Extension of reporting arrangements to advance events in the Research sector (CRM) Proposals developed by Q3 2017/18

Preventative

Prioritisation of import licence assessments as a Q4 activity for HTA staff

Establishments assessed in order of existing risk profile and level of activity

Preventative

Fundamental review of the People Strategy Q1 2018/19

Preventative

Strengthening horizon scanning arrangements (HL) by Q3 2017/18

Preventative

Embed Better Regulation initiatives in the regulatory model (HL) by Q3 2017/18

Preventative

1 Failure to regulate in a manner that maintains public safety and confidence and is appropriate

(Risk to Delivery objectives a-c & d & Development objectives e-d)

Risk Owner: Allan Merrill-Smith

Causes

• Failure to identify regulatory non-compliance
• Regulation is not transparent, accountable, proportionate, consistent and targeted
• Regulation is not sufficiently agile to respond to changes in sectors
• Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting (including Independent Assessors (IAs))
• Inadequate adherence to agreed policies and procedures in particular in relation to decision making
• Poor quality or out of date policies and procedures
• Failure to identify new and emerging issues within HTA remit
• Failure to properly account for Better Regulation
• Insufficient funding in regulated sectors
• Unable to assess all relevant establishments against the new Import and Coding regulations ahead of 31 March 2018 deadline

Effects

• Loss of public confidence
• Compromises to patient safety
• Loss of support from regulated sectors potentially leading to challenge to decisions and non-compliance
• Regataional damage
• Increases in the number of major and critical shortfalls

Risk to Delivery objectives a-c & d & Development objectives e-d

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<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>
</tr>
</thead>
<tbody>
<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><strong>Cause</strong></td>
<td>5 3 Future, should event occur</td>
<td>3 2 Filled identified business-critical roles</td>
<td>1 2 3</td>
<td>Preventative</td>
<td>Monthly reports to HTAMG</td>
<td></td>
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<td>Last report October 2017</td>
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<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>
<td><strong>Effect</strong></td>
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<td>• caused by deficiency in the HTA’s regulation or operation</td>
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<td>• that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)</td>
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<td>Risk owner:</td>
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<td></td>
<td></td>
<td></td>
<td>Chris Birkett</td>
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**Factors to Consider**

- **Insufficient capacity and/or capability** (for instance, staff availability, multiple incidents or ineffective knowledge management)
- **Failure to recognise the potential risk caused by an incident** (for instance, poor decision making, lack of understanding of sector, poor horizon scanning)
- **Failure to work effectively with partners/other organisations**
- **Breach of data security**
- **IT failure or attack incident affecting access to HTA office**

**Effect**

- **Loss of public confidence**
- **Reputational damage**
- **Legal action against the HTA**
- **Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:**
  - relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)
  - caused by deficiency in the HTA’s regulation or operation
  - where we need to regulate, such as with emergency mortuaries
  - that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)

**Risk owner:**

Chris Birkett
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Failure to manage public and professional expectations of human tissue regulation in particular from limitations in current legislation and potential inadequacy of HTA regulatory reach</td>
<td>Risk Owner: Hazel Lofty</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 3</td>
<td>Monitoring</td>
<td>Ongoing top</td>
<td>Log in place and reviewed at HTAMS quarterly. New issues identified in causes and effects</td>
<td></td>
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<td></td>
<td>Matters which certain stakeholder groups believe require review</td>
<td></td>
<td></td>
<td>Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope</td>
<td>X</td>
<td>Preventative/ Detective</td>
<td>Stakeholder Group meeting</td>
<td>Last stakeholder group meeting in October 2017. Public Authority meeting in June 2017</td>
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<tr>
<td></td>
<td>Scope of relevant material e.g. waste products</td>
<td></td>
<td></td>
<td>Active management of issues raised by the media – including the development of the HTA position on issues</td>
<td>X</td>
<td>Preventative/ Detective</td>
<td>Quarterly reports to Authority on communication (including media) activities</td>
<td>Last report in September 2017 - satisfactory</td>
<td></td>
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<td></td>
<td>Licensing requirements e.g. transplantation research</td>
<td></td>
<td></td>
<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
<td>Preventative</td>
<td>Only and its uses understood by SMT and Chair</td>
<td>The duty has not been asked upon in the current business year</td>
<td></td>
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<td></td>
<td>Regulation relating to child bone marrow donation</td>
<td></td>
<td></td>
<td>Legal advice now gives a clearer view of our Schedule 2, s. 20 powers</td>
<td>X</td>
<td>Preventative</td>
<td>Legal advice to be followed</td>
<td>Legal advice September 2016</td>
<td></td>
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<td></td>
<td>Issues raised by emergence of social media e.g. non-related donors</td>
<td></td>
<td></td>
<td>Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidelines)</td>
<td>X</td>
<td>Preventative</td>
<td>Project management, monthly HTAMG updates, quarterly update in Delivery Report</td>
<td>Delivered</td>
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<td></td>
<td>Strengthening of civil sanctions for non-compliance</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td></td>
<td>Whether adhering to the new import and exiting regimes is necessary or a good use of time given Brexit uncertainty</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
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<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Matters which stakeholders/patients may expect to be inside regulatory scope</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
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<td>Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure</td>
<td></td>
<td></td>
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<td>Police holdings</td>
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<td>Products of conception and fetal remains</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td></td>
<td>Data generated from human tissue</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
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<td>Funeral directors</td>
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<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Forensic research facilities</td>
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<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Cryptos</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
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<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Body donors / Taphonomy</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
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<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Imported material</td>
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<td>Other</td>
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<td>X</td>
<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Inadequate stakeholder management</td>
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<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td></td>
<td>Distributed professional confidence in the adequacy of the legislation</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
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<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td></td>
<td>Reduced public confidence in regulation of matters relating to human tissue</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
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<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>Reputational damage</td>
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<td>Clear view of use of s.13 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge</td>
<td>X</td>
<td>Preventative</td>
<td>Project plan presented to HTAMG Q2 2017/18</td>
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<td>EXISTING Controls/Mitigations</td>
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<tr>
<td>4</td>
<td>Failure to utilise people, data and business technology capabilities effectively</td>
<td>• Lack of knowledge about individuals’ expertise</td>
<td>4 4</td>
<td>People</td>
<td>Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle</td>
<td>4 3</td>
<td>Preventative/ Monitoring</td>
<td>x x</td>
<td>SMS reminders as policies due for review. SMT review of all revised policies</td>
<td>Currently in the middle of a regular review cycle</td>
</tr>
<tr>
<td></td>
<td>(Risk to Delivery objectives a-d)</td>
<td>• Poor job and organisational design resulting in skills being under used</td>
<td></td>
<td>Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review)</td>
<td></td>
<td>Preventative/ Monitoring</td>
<td>x x</td>
<td>PDP guidance reviewed annually and approved by SMT, newly introduced countersigning officer check</td>
<td>Guidance issued April 2017</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Risk to Development objectives a-d)</td>
<td>• Poor line management practices</td>
<td></td>
<td>Standard objectives for all line managers</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>(Risk to Deployment objectives a &amp; c)</td>
<td>• Poor leadership from SMT and Heads</td>
<td></td>
<td>Regular review of HTA organisational structure and job descriptions</td>
<td></td>
<td>Preventative</td>
<td>x x</td>
<td>Recruiting to the currently agreed organisational structure and approved job descriptions</td>
<td>Last review completed in Autumn 2015. Job descriptions reviewed as posts become vacant</td>
<td></td>
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<tr>
<td>Risk Owner: Allan Marriott-Smith</td>
<td></td>
<td>• Data holdings poorly managed and under exploited</td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td></td>
<td>Monitoring/ Detective</td>
<td>x x</td>
<td>Staff survey, exit interviews, staff forum (attended by SMT Member and Head of HR)</td>
<td>Report of exit interview presented to Authority in September 2017 Staff Survey will be launched in November 2017 ARAC chair regularly discusses staff issues with chair of staff forum.</td>
<td></td>
</tr>
<tr>
<td>Effect</td>
<td>• Poor deployment of staff leading to inefficient working</td>
<td></td>
<td>Data</td>
<td>Data relating to establishments securely stored with the Customer Relationship Management System (CRM)</td>
<td></td>
<td>Preventative/ Monitoring</td>
<td>x x</td>
<td>Upgrades to CRM, closely managed changes to CMR development. Internal audit of personal data security</td>
<td>GDPR audit will be completed by May 2018</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>• Disaffected staff</td>
<td></td>
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<td></td>
<td></td>
<td>• Increased turnover leading to loss of staff</td>
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<td></td>
<td></td>
<td>• Knowledge and insight that can be obtained from data holdings results in poor quality regulation or opportunities for improvement being missed</td>
<td></td>
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<td></td>
<td></td>
<td>• Poor use of technology resulting in inefficient ways of working</td>
<td></td>
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<td></td>
<td></td>
<td>• Inadequate balance between serving Delivery and Development objectives</td>
<td></td>
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<td></td>
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<tr>
<td>Business technology</td>
<td></td>
<td>Staff training in key business systems</td>
<td>X</td>
<td></td>
<td></td>
<td>Preventative</td>
<td>Systems training forms part of the induction process for new starters</td>
<td>Ongoing records of all new starters trained in key business systems</td>
<td></td>
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</tr>
<tr>
<td></td>
<td></td>
<td>IT systems protected and assurances received from 3rd party suppliers that protection is up to date</td>
<td>X x</td>
<td></td>
<td>Preventative/ Monitoring</td>
<td>Quarterly assurance reports from suppliers. Monthly operational cyber risk assessments. Annual SIRO report</td>
<td>Annual SIRO report presented to ARAC May 2017.</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>ITAMG Development schedule to be part of monthly meetings throughout 2017/18</td>
<td>X</td>
<td></td>
<td>Preventative</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>People</td>
<td></td>
<td>Development of new People strategy and organisational structure in Quarter 1 of 2018/19 business year</td>
<td>X</td>
<td></td>
<td>Preventative</td>
<td>Currently identifying opportunities to collaborate with others in the ALB sector to tap into these opportunities</td>
<td>NHSBT Training - Effective Line Manager one of suite of training days taken up (Aug-17)</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>GDPR project underway to ensure data is compliant with new regulations - GDPR deadline 25 May 2018</td>
<td>X</td>
<td></td>
<td>Preventative</td>
<td></td>
<td></td>
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<tr>
<td>Business technology</td>
<td></td>
<td>Identify refresh training and targeted software specific training needs - linked to roll out of new IT hardware for HTA users in Q4 of 2017/18 business year (85)</td>
<td>X</td>
<td></td>
<td>Preventative</td>
<td></td>
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<td>REF</td>
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<tr>
<td>5</td>
<td>Insufficient, or ineffective management of, financial resources</td>
<td>Cause</td>
<td>4</td>
<td>Ongoing</td>
<td>Budget management framework to control and review spend and take early action</td>
<td>2 3</td>
<td>X</td>
<td>Monitoring</td>
<td>All</td>
<td>Periodic financial reporting to SMT and Authority</td>
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<tr>
<td></td>
<td>Risk Owner: Richard Sydee</td>
<td>Effect</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td>Fee payers unable to pay licence fees</td>
<td>6</td>
<td></td>
<td>Financial projections, cash flow forecasting and monitoring</td>
<td></td>
<td></td>
<td>Monitoring</td>
<td></td>
<td>Last quarterly report Oct/Nov 2017</td>
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<tr>
<td></td>
<td></td>
<td>The number of licenced establishments changes, leading to reduced fee income</td>
<td></td>
<td></td>
<td>Licence fee modelling</td>
<td></td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Update agreed by the Authority November 2017</td>
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<td></td>
<td></td>
<td>Management fail to set licence fees at a level that recover sufficient income to meet resource requirements</td>
<td></td>
<td></td>
<td>Rigorous debt recovery procedure</td>
<td></td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Last quarterly report Oct/Nov 2017</td>
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<tr>
<td></td>
<td></td>
<td>Failure to estimate resource required to meet our regulatory activity</td>
<td></td>
<td></td>
<td>Reserves policy and levels reserves</td>
<td></td>
<td></td>
<td>Monitoring</td>
<td></td>
<td>Last agreed February 2017</td>
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<tr>
<td></td>
<td></td>
<td>Poor budget and/or cash-flow management</td>
<td></td>
<td></td>
<td>Delegation letters set out responsibilities</td>
<td></td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Issued in April 2017</td>
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<td></td>
<td></td>
<td>Unexpected increases in regulatory responsibilities</td>
<td></td>
<td></td>
<td>Prioritisation when work requirements change</td>
<td></td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Last HTAMG report September 2017</td>
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<td></td>
<td></td>
<td>Unforeseeable price increases / reductions in GIA</td>
<td></td>
<td></td>
<td>Fees model provides cost/income information for planning</td>
<td></td>
<td></td>
<td>Preventative</td>
<td></td>
<td>Update to be agreed by the Authority November 2017</td>
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<td></td>
<td></td>
<td>Payments to suppliers and/or staff delayed</td>
<td></td>
<td></td>
<td>Annual external audit</td>
<td></td>
<td></td>
<td>Detective</td>
<td>NAO report annually</td>
<td>Last report in June 2017 - clean opinion</td>
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<td></td>
<td></td>
<td>Compensatory reductions in staff and other expenditure budgets</td>
<td></td>
<td></td>
<td>Monitoring of income and expenditure (RS)</td>
<td></td>
<td></td>
<td>Detective</td>
<td>Monthly finance reports to SMT and quarterly to Authority</td>
<td>Last quarterly report March 2017</td>
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<td></td>
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<td>Increased licence fees</td>
<td></td>
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<td>Ongoing</td>
<td></td>
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<td>Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS)</td>
<td>Last FDs meeting Dec 2016</td>
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<td></td>
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<td>Requests for further public funding</td>
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<td>Draw on reserves</td>
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<td>Leading to:</td>
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<td>Inability to deliver operations and carry out statutory remit</td>
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## Authority Report

### Delivery – Quarter Three 2017/18

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<td><strong>Paper Reference</strong></td>
<td>HTA (03/18)</td>
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<tr>
<td><strong>Author</strong></td>
<td>Christopher Birkett / Hazel Lofty</td>
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<tr>
<td><strong>Author Contact</strong></td>
<td><a href="mailto:Christopher.Birkett@htat.gov.uk">Christopher.Birkett@htat.gov.uk</a> <a href="mailto:Hazel.Lofty@hta.gov.uk">Hazel.Lofty@hta.gov.uk</a></td>
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### Strategic Objectives (Delivery)

1. Deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to public confidence.
2. 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.
3. Deliver effective regulation of living donation.
4. 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.
5. Maintain our strategic relationships with other regulators operating in the health sector.

### Relevant Key Performance Indicators (KPIs)

1. At least 210 site visits to take place during the business year across all sectors.
2. 100% of Corrective and Preventative Actions (CAPAs) implemented to address major and critical shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented.
3. 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days.
4. 100% of panel cases turned around within ten working days.
5. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries.
6. Report provided to the Authority annually (in May / June 2018) on a series of measures, which provide an overview of safety in the regulated sectors.

### Related Strategic Risks

1. Failure to regulate appropriately (Objectives A-C & E)
2. Failure to manage an incident (All objectives)
3. Failure to manage expectations of regulation (Objective D)
4. Failure to utilise our capabilities effectively (Objectives A-D)

(See paper HTA (02/18) Annex A for detailed information)*

*Note: Based on the Strategic Register last updated January 2018 to reflect the latest scoring and reformatting or the register.
Purpose of paper

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

2. It is provided as a source of assurance on the delivery activities of the HTA, including statistics and background information set out in Annex A. Annex B reports Serious Adverse Events and Adverse Reactions (SAEARs) and HTA Reportable Incidents (HTARIs).

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 25 January 2018.

Action required

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

Directors’ summary

5. The clustering of critical shortfalls in quarter two has not been repeated in quarter three. We are analysing our findings for the PM sector inspections undertaken against the revised licensing standards, the initial findings being shared for discussion with the Histopathology Working Group.

6. During quarter three, we agreed and implemented our plan for inspections during quarter four, which will ensure we meet our inspection commitments for the business year while also meeting our non-inspection business needs.

Critical shortfalls

7. No critical shortfalls were identified during quarter three.

8. By way of a reminder, five critical shortfalls were identified during three post mortem sector inspections carried out in quarter two.

   - One establishment had three critical shortfalls, which related to disposal practices, traceability and auditing of retained tissue.
   - One establishment had one critical shortfall relating to tissue not being disposed of as soon as reasonably possible, once it has been identified as no longer required.
• One establishment had one critical shortfall as a result of a number of major shortfalls against their premises.

9. All establishments with critical shortfalls are progressing well against their CAPA plans.

Investigations

New investigations

10. There were no new investigations in quarter three.

Update on investigation reported in previous Delivery report (HTA 38/17)

Investigation 01/17

11. We received an anonymous complaint about lone working practices in the mortuary of an HTA-licensed establishment. We were informed that lone working had been taking place in the mortuary for several weeks and concerns were expressed about the impact of this on the staff member and the conduct of mortuary duties.

12. We have sought and obtained assurances from the Designated Individual (DI) that there is a suitable governance framework in place, which addresses staffing levels and mitigates the risk of a serious incident occurring as a result of lone working.

13. The investigation remains active as we are working through a CAPA plan with the establishment and will close the case once we have agreed confirmation that there are sufficient permanent staff in place to carry out all the necessary activities under the licence. On current commitments, we anticipate this will be by the end of February.

Investigation 03/17

14. A third investigation was prompted by several historical concerns being raised by current and former members of staff at a HTA-licensed establishment. Broadly, these included concerns about the inappropriate use of samples and PM imaging.

15. The investigation took into account a large amount of information that was provided to us, from both parties, in emails, submitted documents, telephone conversations and face-to-face meetings. The investigation concluded towards the end of quarter three, the HTA being assured that there were no reasons to pursue these matters any further in relation to our regulatory remit.

Investigation 09/16
16. In previous reporting, there was an investigation into an enquiry regarding services offered by an establishment, where an activity was being carried out on licensed premises, but not under the governance of the licence. As a result, we stopped all activities.

17. Following confirmation that activities have ceased, this case has been closed. A wider body of policy work is currently being undertaken with the MHRA relating to the regulatory oversight of similar activities.

Non-routine site visit inspections

18. There was one non-routine site visit inspection in quarter three, which was carried out at shortened notice.

19. The HTA conducted a non-routine inspection of an establishment in the post mortem sector in November, following concerns raised by an individual and information provided to the HTA by the establishment in their compliance update. The issues raised were predominantly in relation to the body storage facilities, equipment in the mortuary and practices around the release of bodies.

20. We found that staff at the establishment were committed to improving practices and were keen to ensure all standards are met; however, although some areas of good practice were identified on the inspection, six major and three minor shortfalls were also identified. These are subject to a CAPA plan.

Police referrals

21. This report includes:

   a. details of the cases considered by SMT that were potential breaches of human tissue legislation;
   b. factors in favour of referral;
   c. factors against referral; and
   d. the decisions made.

Police referral 05/17

22. Concerns were raised about an establishment that had undertaken distribution and export of adipose tissue without formal authorisation from the HTA. The HTA acknowledged the Designated Individual’s contention that he was unaware that these activities required licensing.
23. In accordance with the HTA’s policy on police referrals, SMT took a number of factors into account in reaching their decision on whether to refer the matter to the police, including:

- the alleged offence had a minimal potential to damage public confidence in the use of human tissue;
- the fact that the person committing the alleged offence is in a position of authority or trust as DI;
- the fact that the person committing the alleged offence acknowledged the breach of human tissue legislation to the Authority and has not attempted to conceal the matter;
- the DI has ceased the activity and so the offence is likely to be continued or repeated; and
- the DI should have known that the activity required authorisation

24. Taking these factors into account, the HTA considered that it is not in the public interest to refer this matter to the police for investigation. We do, however, have significant concerns about the fact that these activities took place without appropriate authorisation. With this in mind, the HTA expects that the DI will take steps to ensure that there are systems in place to prevent a recurrence of this issue.

**Police referral 06/17**

25. Concerns were raised with us regarding the removal of tissue during a post-mortem examination without appropriate consent.

26. After careful review of the facts of this complicated case, the HTA considered the factors for and against a police referral in line with our policy. We concurred with the assessment that the following factors against referral appear relevant:

- The alleged offence poses no risk to public safety
- The alleged offence has limited potential to damage public confidence in the use of human tissue
- A person committing the alleged offence acknowledged the breach of human tissue legislation to the Authority and the person concerned has not attempted to conceal the matter
- The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment
- It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding
27. We considered that there was one factor in favour of referral, that the alleged offence has the potential to damage public confidence in the use of human tissue, although it had not done so in this case.

28. The HTA concluded that, on balance, the factors against referral outweighed those in favour, and decided that no referral would be made in this case.

Legal notices

29. No Directions were issued in quarter three.

Regulatory decision meetings

30. Two regulatory decision meetings (RDMs) were held in quarter three

RDM one

31. The RDM was held to discuss the inspection findings of an establishment in the post mortem sector. The RDM discussions helped to inform the drafting of the inspection report and the approach to take to address our concerns. It was decided that the shortfalls identified will be addressed through a corrective and preventative action plan and if this is not met by the establishment to then reconvene to discuss our next approach. Satisfactory progress has been made to date.

RDM two

32. The RDM was convened to discuss an establishment in the Human Application sector, who had undertaken distribution and export of adipose tissue without formal authorisation from the HTA. Please see Police referral 05/17 above for further information on why it was decided we would not be referring this case to the police.

Reconsiderations, representations and appeals

33. No reconsiderations, representations or appeals were considered during quarter three.

Other regulatory activity

MHRA Field Safety Notice

34. The HTA was notified by the Medicines and Healthcare products Regulatory Agency (MHRA) of a Field Safety Notice that had been issued by the manufacturer regarding a small number of batches of HIV-I testing kits manufactured by that company.
35. This product is used for monitoring the progress of HIV in diagnosed patients and is not used for first diagnosis; however, an email was sent to all relevant DIs in the HA sector, and all named contacts in the ODT sector, to reinforce awareness of the Field Safety Notice, and ensure it was circulated to the relevant staff.

Charity based in Israel

36. Legal advice was sought in relation to a charity based in Israel. The charity matches living kidney donors with recipients; a handful of UK residents have used the services of the charity to help facilitate a donation. It has come to our attention that the charity has, according to press reports in Israel, become the subject of a governmental/criminal investigation in Israel in relation to money being provided for transplants.

37. Legal advice was clear that, on the basis of what is known at the moment, the HTA should continue to review these cases as we receive them. All of these cases will be referred to an HTA panel for assessment.

Living donor transplant without approval

38. Members will recall that during quarter two we were notified of a living donor organ transplant, which had proceeded without HTA approval.

39. A letter has been sent to the establishment outlining the serious nature of the incident, and a thorough root cause analysis (RCA) report has been undertaken by them. We continue to liaise with the establishment and have provided our comments on the RCA. We are satisfied, as a result, that appropriate steps have been taken which mitigate the risks of something similar happening again. The new procedures will also be reviewed during the audit of the establishment, which is happening in quarter four.

Enquiries

General enquiries

40. During quarter three, we recorded 794 general enquiries, compared to 650 in the previous quarter. The enquiries included:

a. 388 from members of the public about body donation (301 were received via email or phone, and in the post, and 87 via the website). This compares to 396 in the previous quarter.

b. 214 from professionals about licensing or other areas of our regulatory work, compared with 193 in the previous quarter.
41. Of these enquiries, 300 were received via the website, compared to 265 last quarter. Other enquiries are usually received by phone.

42. The HTA sets itself a KPI of responding to 95 percent of general enquiries in ten working days. Of enquiries received during quarter three, 96 percent were closed in our case management system within ten working days, compare to 95 percent in the previous quarter. Over quarter three, three percent of enquiries were responded to within twenty working days, with the average time taken standing at five days. The cases that fell outside ten working days generally tended to involve complex licensing enquiries and concerns raised with us about establishments.

Freedom of Information Act (FOIA) requests

43. We had nine FOIA requests in quarter three, compared to four in the previous quarter. We publish FOIA responses on our website. The subjects for each request were:

   a. The number of post-abortive pregnancy remains registered between June 2016 and June 2017.
   b. Complaints to the HTA about temperature excursions.
   c. Paediatric organ donation applications, approvals and rejections.
   d. Expenditure over £25k.
   e. HTA finance systems.
   f. HTA video conferencing technology.
   g. Serious incidents in Scotland.
   h. Private companies used for HTA communications.
   i. HTA incident reports for lost, missing or stolen human tissue.

Stakeholder engagement

Codes implementation review survey

44. During Q4, we produced a survey seeking views from establishments on the implementation of the revised codes and standards as part of the Codes and Standards Implementation Review. We received 116 responses in total, predominantly from stakeholders in the Post Mortem and Research sectors. Overall, respondents were positive about the new codes of practice although some suggestions have been made which will be used to inform future development activities. Further information on the review is given in the Development report.

Winter capacity guidance

45. In November, we emailed stakeholders in the post mortem sector with updated guidance on capacity and contingency arrangements in mortuaries. In order to help
establishments prepare for the winter months, we combined previous recommendations, along with updated and new recommendations and published these on the website.

46. The recommendations cover the following areas:

- Fridge and freezer storage, including:
  - Storage of bariatric bodies
  - Storage temperature monitoring
- Contingency storage
  - Transfers of bodies to other premises
  - Transfer to funeral directors
- Mutual Aid Agreements
- National Resilience
- Factors contributing to increased pressures on storage capacity
  - Winter deaths
  - Flow of bodies after approval for release
  - Storage capacity and funding requests

**HTA Fees 2018/19**

47. On 11 December 2017, we announced licence fee levels for the 2018/19 business year. We published the final breakdown of fees including the rationale behind the fees increase on the website. We also emailed Designated Individuals and licence contacts across all sectors regarding the announcement.

48. We have received little or no feedback so far regarding the 2018/19 fees, but we will continue to remind establishments of the changes to their licences fees on the run up to April 2018.

**Import and coding Directives**

49. In December, the Department of Health and Social Care (DHSC) published the Government’s response to the consultation on Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017 transposing the coding and import Directives for tissues and cells into UK law. Further information on the project is given in the Development report.

50. To coincide with the publication of the consultation response, we notified stakeholders in the human application sector about our updated guidance on the Directives. The guidance was reviewed following the feedback we received from DHSC’s consultation.
We also updated the information available on the website, with additional guidance on how establishments can comply with the Directives.

Digital communications and publications

51. Following comprehensive internal review, we published lay guides to the HTA Codes of Practice in quarter three. The aim of the guides is to set out the basic rights a person has when dealing with an establishment regulated by the HTA. This includes who can give consent for different activities, rights to information and options for using and disposing of tissue. The guides also explain how the use of human tissue is regulated in England, Northern Ireland and Wales.

52. The guides were published on the HTA website and circulated via our public and professional e-newsletters. The guides have been well received by both public and professional stakeholders. They will undergo continual review by our public review panel and revised versions will be shared with the Stakeholder and Fees Group.

Delivery KPI narrative

Performance against 2017/18 KPIs

53. KPI 2 was red for each month of quarter three. In October, five of seven major shortfalls were completed on time. The overdue two were for the same establishment and were completed two and three working days after the deadline. In November, three of seven major shortfalls were completed on time. The four overdue were for the same establishment: two have since been closed, one is in the process of being assessed, with a view to closure, and one remains open. This one has since received an extension to February as the CAPA evidence was not sufficient to provide assurance. In December, six of 13 major and critical shortfalls were completed on time. Of the seven overdue, six were for the same establishment with which we have been working very closely, and were all closed off between three and seven days after their deadlines. The final shortfall is in the process of being closed, as we have been fully assured by the evidence submitted.

54. All other Delivery KPIs for quarter three are within target or tolerance and marked as green.
Annex A – Statistics and background information

Regulation

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

<table>
<thead>
<tr>
<th>Type of site visit</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine inspection</td>
<td>38</td>
<td>41</td>
<td>42</td>
<td>39</td>
<td>136</td>
<td>164</td>
</tr>
<tr>
<td>LAAV - new application</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>4</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Satellite site inspection</td>
<td>10</td>
<td>23</td>
<td>0</td>
<td>16</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td>CAPA follow up</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>8</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Non-routine inspection</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Total sites visited</td>
<td>55</td>
<td>72</td>
<td>59</td>
<td>51</td>
<td>202</td>
<td>234</td>
</tr>
</tbody>
</table>

Table Two: HTARIs in the post-mortem sector

55. In 2014/15, mortuaries licenced by the HTA admitted around 330,000 bodies, and performed over 100,000 post-mortem examinations. The number of reported HTARIs in context is very low.

56. At the previous Authority meeting, Members requested that the ‘Any adverse incident’ category was reviewed to ensure that no new categories were emerging. This has been carried out by the HTARI team as part of a wider review of HTARI data. No substantive issues have been found, but some amendments have been identified which will improve the data quality. The HTARI team will continue to keep this category under review, and any new classifications taken to HWG for further discussion. Classification and summaries of closed incidents are included below and in Annex B.

<table>
<thead>
<tr>
<th>HTARI Classification</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental damage to a body</td>
<td>15</td>
<td>7</td>
<td>10</td>
<td>13</td>
<td>37</td>
<td>34</td>
</tr>
<tr>
<td>Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>
### Table Three: SAEARs in the human application sector

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event linked to Distribution</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to Materials</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to Preservation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Processing</td>
<td>3</td>
<td>3</td>
<td>8</td>
<td>2</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Event linked to Procurement</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>5</td>
<td>21</td>
<td>9</td>
</tr>
<tr>
<td>Event linked to Storage</td>
<td>2</td>
<td>5</td>
<td>2</td>
<td>2</td>
<td>11</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Testing</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

57. Given the nature of regulated activities carried out in the human application sector, it is difficult to calculate a total number of activities to establish a denominator to compare with numbers of events and reactions.
| Event linked to Transportation | 1 | 1 | 0 | 0 | 2 | 2 |
| Event linked to Other process | 2 | 4 | 2 | 7 | 13 | 5 |
| Reaction in Donor              | 0 | 1 | 1 | 1 | 1 | 3 |
| Reaction in Recipient          | 0 | 7 | 2 | 5 | 19 | 16 |
| Total                          | 17 | 29 | 19 | 24 | 93 | 60 |

Table Four: SAEARs in the Organ Donation and Transplantation sector

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events</td>
<td>5</td>
<td>8</td>
<td>10</td>
<td>10</td>
<td>37</td>
<td>22</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>7</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>12</td>
<td>12</td>
<td>17</td>
<td>63</td>
<td>36</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Approvals</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2016/17</th>
<th>Q4 2016/17</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvals</td>
<td>11</td>
<td>17</td>
<td>14</td>
<td>25</td>
<td>69</td>
<td>55</td>
</tr>
</tbody>
</table>
### Table Six: Living organ donation cases

<table>
<thead>
<tr>
<th>Type of case</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of cases considered</td>
</tr>
<tr>
<td></td>
<td>Approvals by the LDAT Panel</td>
</tr>
<tr>
<td></td>
<td>Approvals by Authority panels</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Q3 17/18</th>
<th>Q2 17/18</th>
<th>Q1 17/18</th>
<th>Q4 16/17</th>
<th>16/17 Total Year</th>
<th>15/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directed kidney</td>
<td>196</td>
<td>210</td>
<td>229</td>
<td>233</td>
<td>874</td>
<td>886</td>
</tr>
<tr>
<td>Directed altruistic kidney</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>19</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>Non-directed altruistic kidney</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>Paired or pooled kidney</td>
<td>34</td>
<td>33</td>
<td>25</td>
<td>15</td>
<td>91</td>
<td>88</td>
</tr>
<tr>
<td>Directed liver lobe</td>
<td>75</td>
<td>43</td>
<td>51</td>
<td>31</td>
<td>113</td>
<td>146</td>
</tr>
<tr>
<td>Non-directed altruistic liver lobe</td>
<td>10</td>
<td>6</td>
<td>10</td>
<td>14</td>
<td>46</td>
<td>42</td>
</tr>
<tr>
<td>Number of cases considered</td>
<td>2</td>
<td>8</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Approvals by the LDAT Panel</td>
<td>321</td>
<td>303</td>
<td>321*</td>
<td>315</td>
<td>1163</td>
<td>1172</td>
</tr>
<tr>
<td>Approvals by Authority panels</td>
<td>208</td>
<td>218</td>
<td>240</td>
<td>248</td>
<td>930</td>
<td>934</td>
</tr>
</tbody>
</table>

**Q3 17/18**
- Directed kidney: 196 cases
- Directed altruistic kidney: 0 cases
- Non-directed altruistic kidney: 2 cases
- Paired or pooled kidney: 34 cases
- Directed liver lobe: 75 cases
- Non-directed altruistic liver lobe: 10 cases
- Number of cases considered: 321
- Approvals by the LDAT Panel: 208
- Approvals by Authority panels: 113

**Q2 17/18**
- Directed kidney: 210 cases
- Directed altruistic kidney: 0 cases
- Non-directed altruistic kidney: 2 cases
- Paired or pooled kidney: 33 cases
- Directed liver lobe: 43 cases
- Non-directed altruistic liver lobe: 6 cases
- Number of cases considered: 303
- Approvals by the LDAT Panel: 218
- Approvals by Authority panels: 85

**Q1 17/18**
- Directed kidney: 229 cases
- Directed altruistic kidney: 0 cases
- Non-directed altruistic kidney: 1 cases
- Paired or pooled kidney: 25 cases
- Directed liver lobe: 51 cases
- Non-directed altruistic liver lobe: 10 cases
- Number of cases considered: 321*
- Approvals by the LDAT Panel: 240
- Approvals by Authority panels: 81

**Q4 16/17**
- Directed kidney: 233 cases
- Directed altruistic kidney: 19 cases
- Non-directed altruistic kidney: 0 cases
- Paired or pooled kidney: 15 cases
- Directed liver lobe: 31 cases
- Non-directed altruistic liver lobe: 14 cases
- Number of cases considered: 315
- Approvals by the LDAT Panel: 248
- Approvals by Authority panels: 67

**16/17 Total Year**
- Directed kidney: 874 cases
- Directed altruistic kidney: 21 cases
- Non-directed altruistic kidney: 3 cases
- Paired or pooled kidney: 91 cases
- Directed liver lobe: 113 cases
- Non-directed altruistic liver lobe: 46 cases
- Number of cases considered: 1163
- Approvals by the LDAT Panel: 930
- Approvals by Authority panels: 233

**15/16 Total Year**
- Directed kidney: 886 cases
- Directed altruistic kidney: 0 cases
- Non-directed altruistic kidney: 7 cases
- Paired or pooled kidney: 88 cases
- Directed liver lobe: 146 cases
- Non-directed altruistic liver lobe: 42 cases
- Number of cases considered: 1172
- Approvals by the LDAT Panel: 934
- Approvals by Authority panels: 238
Communications

Social media

58. In quarter three, the HTA’s Twitter account had 1827 followers, up from 1784 in the previous quarter. Our engagement rate stayed at to 1.2%, with a peak rate of 7.8%. On average, HTA tweets were seen by 435 people per day.

Table Seven:

<table>
<thead>
<tr>
<th>Month</th>
<th>Impressions</th>
<th>Profile Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>16.7K</td>
<td>1,221</td>
</tr>
<tr>
<td>November</td>
<td>10.9K</td>
<td>934</td>
</tr>
<tr>
<td>December</td>
<td>12.2K</td>
<td>1,304</td>
</tr>
</tbody>
</table>

59. Tweets with the highest reach and engagement in quarter three were about:

a. **Post mortem**
   Death Before Birth’s report on the HTA pregnancy remains guidance.

b. **Organ donation and transplantation**
   Launch of DHSC’s consultation on an opt-out system in England.

c. **Corporate**
   Launch of public guides to HTA Codes of Practice.

d. **Corporate**
   Regulation Manager vacancy advert

e. **Anatomy/organ donation and transplantation**
   Information on body donation and signing up for organ donation.

f. **Human application**
   Promotion of HTA cord blood guidance on world cord blood day.

g. **Public display**
   Information on inspection report function on the website.

60. There are 765 Facebook ‘likes’ on the HTA page, up from 742 in quarter two. The HTA also had 517 followers for its LinkedIn company page, up from 494 in quarter two.
Table Eight: Digital users

<table>
<thead>
<tr>
<th></th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2017/18</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users</td>
<td>55,723</td>
<td>49,725</td>
<td>62,191</td>
<td>55,155</td>
<td>199,226</td>
<td>165,032</td>
</tr>
<tr>
<td>Page views</td>
<td>243,507</td>
<td>214,622</td>
<td>190,651</td>
<td>239,530</td>
<td>781,047</td>
<td>729,300</td>
</tr>
<tr>
<td>Pages viewed per session</td>
<td>2.69</td>
<td>2.95</td>
<td>3.02</td>
<td>3.12</td>
<td>3.13</td>
<td>3.38</td>
</tr>
<tr>
<td>Average session duration</td>
<td>00:02:27</td>
<td>00:02:33</td>
<td>00:02:43</td>
<td>00:02:56</td>
<td>00:02:50</td>
<td>00:02:56</td>
</tr>
<tr>
<td>Online enquiries</td>
<td>289</td>
<td>268</td>
<td>234</td>
<td>411</td>
<td>1,396</td>
<td>1,448</td>
</tr>
<tr>
<td>eNewsletter signups</td>
<td>396</td>
<td>381</td>
<td>343</td>
<td>519</td>
<td>1,515</td>
<td>938</td>
</tr>
</tbody>
</table>

61. The highest viewed pages are:

Table Nine: Page views

<table>
<thead>
<tr>
<th>Highest viewed pages</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>Q1 2017/18</th>
<th>Q4 2017/18</th>
<th>2016/17 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body donation FAQs</td>
<td>8,478</td>
<td>7,518</td>
<td>8,226</td>
<td>13,288</td>
<td>59,753</td>
</tr>
<tr>
<td>Medical school search</td>
<td>12,772</td>
<td>13,493</td>
<td>12,152</td>
<td>17,283</td>
<td>57,040</td>
</tr>
<tr>
<td>Donating your body info</td>
<td>17,042</td>
<td>17,241</td>
<td>14,059</td>
<td>16,570</td>
<td>40,819</td>
</tr>
<tr>
<td>Guidance for professionals</td>
<td>5,664</td>
<td>5,368</td>
<td>5,337</td>
<td>5,670</td>
<td>22,847</td>
</tr>
</tbody>
</table>

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

a. Donating your body – 1.5K;
b. Guidance for professionals – 2K; and
c. Codes of Practice and Standards – 1.5K

Newsletters

62. The HTA sent out a professional newsletter and an Independent Assessor bulletin in November. The HTA public newsletter was sent out in October and December.

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

---

1 Data first collected in 2016/17
### Table 10: Professional newsletter

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2017</td>
<td>4176</td>
<td>32%</td>
</tr>
<tr>
<td>September 2017</td>
<td>3133</td>
<td>30%</td>
</tr>
<tr>
<td>July 2017</td>
<td>3076</td>
<td>28%</td>
</tr>
<tr>
<td>May 2017</td>
<td>3966</td>
<td>27%</td>
</tr>
<tr>
<td>March 2017</td>
<td>3571</td>
<td>31%</td>
</tr>
<tr>
<td>January 2017</td>
<td>3461</td>
<td>30%</td>
</tr>
</tbody>
</table>

### Table 11: Independent Assessor bulletin

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 2017</td>
<td>272</td>
<td>35%</td>
</tr>
<tr>
<td>July 2017</td>
<td>272</td>
<td>25.7%</td>
</tr>
<tr>
<td>May 2017</td>
<td>273</td>
<td>31.5%</td>
</tr>
<tr>
<td>January 2017</td>
<td>261</td>
<td>48%</td>
</tr>
<tr>
<td>November 2016</td>
<td>153</td>
<td>49%</td>
</tr>
<tr>
<td>August 2016</td>
<td>153</td>
<td>41%</td>
</tr>
</tbody>
</table>

### Table 12: Public newsletter

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2017</td>
<td>1163</td>
<td>38%</td>
</tr>
<tr>
<td>October 2017</td>
<td>1086</td>
<td>29%</td>
</tr>
<tr>
<td>July 2017</td>
<td>997</td>
<td>42%</td>
</tr>
<tr>
<td>April 2017</td>
<td>903</td>
<td>49%</td>
</tr>
<tr>
<td>February 2017</td>
<td>697</td>
<td>42%</td>
</tr>
<tr>
<td>December 2016</td>
<td>686</td>
<td>42%</td>
</tr>
<tr>
<td>October 2016</td>
<td>668</td>
<td>44%</td>
</tr>
</tbody>
</table>

64. We will continue to monitor and test these emails to consistently achieve high open rates.
65. During quarter three, coverage which directly mentioned the HTA included:

a. Prime Minister Theresa May announces intent to consult on a change to the organ donation system in England to an opt-out system.

Initial Media Coverage of the Prime Minister’s Opt Out Announcement:

Victory! Organ donation change to Opt Out system in stunning victory for seriously ill transplant patients (The Mirror) | England to consider opt out organ donation (BBC News) | Theresa May's organ donation reform sends a chilling message: that the state owns your body unless you opt out (The Telegraph) | Doctors praise plan for organ donor presumed consent in England (The Guardian) | TRANSPLANT HOPES: Prime Minister Theresa May vows to 'shift to opt-OUT organ donation system' in England (The Sun) | Opt out if you DON’T want to donate your organs: Theresa May announces plans to make it easier for doctors to take them without consent (Daily Mail) | The Tories want to nationalise your bodily organs (Catholic Herald)

b. Families that experience pregnancy loss deserve higher standards of care (The Conversation)

The Death Before Birth project's report has identified the problems experienced by grieving parents of miscarriages and pregnancy loss. One major concern is that communication with parents is not always sensitive, and medical professionals can lack the specific training required. This article mentions our pregnancy remains guidance and our involvement in this area.

c. How and why Reuters purchased body parts (Reuters.com | US) & Special Report - Reuters buys human remains, and learns a donor's tragic story (Investing.com | US); also covered by the MailOnline (UK)

Reuters spent more than a year examining the workings of a multi-million dollar industry that dissects, rents and sells human bodies.

d. Media coverage of the HTA inspection findings at University Hospital of Wales in Cardiff: A statement was been issued by the Welsh Government. There was coverage by the BBC (including a video interview with the Chief Executive), the Mirror and ITV News.

e. Serious incidents after death: content analysis of incidents reported to a national database (Journal of the Royal Society of Medicine)

A report published in the Journal of the Royal Society of Medicine on an
investigation of serious incidents occurring in the management of patient remains after death.

The report above led to the following coverage:
Dead bodies returned to wrong families in litany of NHS mortuary errors - major new report (Telegraph) | Mortuary errors 'avoidable if bodies treated like living patients' (Guardian) | Dead bodies returned to wrong families, report on NHS mortuary practices reveals (London Evening Standard) | Post-Mortems Conducted On Wrong Bodies, Study Reveals (Clinical Services Journal) | Families buried wrong bodies after NHS mortuary mix-ups, study reveals (Independent).

Liver surgeon Simon Bramhall marked initials on patients (BBC News)
A surgeon who marked his initials on the livers of two transplant patients has admitted assault.
## Human Application – Serious Adverse Events

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Process Event Linked To</th>
<th>Description of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-39621-T6S0</td>
<td>Processing</td>
<td>Contaminant found in both post processing and post infusion sample. Patient engrafted without incident.</td>
</tr>
<tr>
<td>CAS-36269-Z4B9</td>
<td>Testing</td>
<td>Samples used for mandatory biological tests were outside their specified conditions for storage.</td>
</tr>
<tr>
<td>CAS-40205-T8J9</td>
<td>Procurement</td>
<td>Expired consumables and reagents were used in a procurement due to insufficient stock control.</td>
</tr>
<tr>
<td>CAS-39477-V2V7</td>
<td>Processing</td>
<td>Contamination of tissue harvest due to operator error. The patient received Antibiotic Prophylaxis.</td>
</tr>
<tr>
<td>CAS-39376-D8K3</td>
<td>Storage</td>
<td>Unit not double bagged and a split detected. All units now double bagged.</td>
</tr>
<tr>
<td>CAS-39374-B2S5</td>
<td>Storage</td>
<td>Vials found at bottom of liquid nitrogen tank in liquid phase. The vials will not be used for clinical application.</td>
</tr>
<tr>
<td>CAS-34639-R0R9</td>
<td>Procurement</td>
<td>Unit tested positive for microbial contamination. Samples in storage pending disposal.</td>
</tr>
<tr>
<td>CAS-35064-K1N5</td>
<td>Processing</td>
<td>Skin contaminant detected in unit of cells. Cells infused under antibiotic cover.</td>
</tr>
<tr>
<td>CAS-39276-Q8S9</td>
<td>Testing</td>
<td>Incorrect test results reported. Recipient tested and shown to be negative and continues to be monitored.</td>
</tr>
<tr>
<td>CAS-36258-D3H3</td>
<td>Transportation</td>
<td>Difficulty in removing frozen cells from shipper resulted in bag split, cells remain in storage pending disposal.</td>
</tr>
<tr>
<td>CAS-40007-J9Q6</td>
<td>Procurement</td>
<td>Procurement procedure led to the presence of skin commensals in tissue/cell harvest.</td>
</tr>
<tr>
<td>CAS-37880-P7K8</td>
<td>Other</td>
<td>Failed engraftment - cells had been stored for a long period of time before they were infused.</td>
</tr>
<tr>
<td>CAS-40182-T3K8</td>
<td>Procurement</td>
<td>Tissue/cell harvest contaminated with skin commensals. No impact on recipient.</td>
</tr>
<tr>
<td>CAS-40512-L8D9</td>
<td>Other</td>
<td>Leak of cells during thawing, remaining cells in bag infused without incident.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Incident Type</td>
<td>Brief description of incident</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------</td>
<td>------------------------------</td>
</tr>
<tr>
<td>CAS-39294-C3L3</td>
<td>Procurement</td>
<td>Contaminated tissue/cell harvest - practices reviewed and training provided and observed by microbiologist.</td>
</tr>
<tr>
<td>CAS-40743-T1M2</td>
<td>Procurement</td>
<td>Infusion of microbiology positive unit - no impact on recipient.</td>
</tr>
<tr>
<td>CAS-39961-N5M5</td>
<td>Procurement</td>
<td>Procurement of tissue/cell undertaken without appropriate TPA in place.</td>
</tr>
</tbody>
</table>

Organ Donation and Transplantation – Serious Adverse Events

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Type</th>
<th>Brief description of incident</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-39662-Y3Y0</td>
<td>ODT SAE</td>
<td>Retrieval damage - organ not transplanted.</td>
</tr>
<tr>
<td>CAS-39275-J8C6</td>
<td>ODT SAE</td>
<td>Retrieval damage - organ not transplanted.</td>
</tr>
<tr>
<td>CAS-40750-H6D0</td>
<td>ODT SAE</td>
<td>Retrieval damage - organ not transplanted.</td>
</tr>
<tr>
<td>CAS-39439-F9F2</td>
<td>ODT SAE</td>
<td>Donor virology sample discrepancy.</td>
</tr>
<tr>
<td>CAS-39428-Y1J2</td>
<td>ODT SAE</td>
<td>Donor identifiers not checked correctly at recipient centre - organ not transplanted.</td>
</tr>
</tbody>
</table>

Organ Donation and Transplantation – Serious Adverse Reactions

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Donor or Recipient</th>
<th>Incident type</th>
<th>Brief description of Reaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-40452-B0N4</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Discrepancy in testing results between transplant centres.</td>
</tr>
<tr>
<td>CAS-38070-Y8C9</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Prolonged hospitalisation for recipient - organ not transplanted.</td>
</tr>
<tr>
<td>CAS-41379-V8Z9</td>
<td>Donor</td>
<td>ODT SAR</td>
<td>Allergic reaction in donor - organ not transplanted.</td>
</tr>
</tbody>
</table>
Recipient treated with anti-virals following transplantation.

Discrepancy in testing results discovered post transplantation.

Post Mortem HTA Reportable Incidents

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Classification</th>
<th>Brief summary of HTARI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-39936-Q4W2</td>
<td>Recipient ODT SAR</td>
<td>Anatomical complications with transplantation led to transplant operation being abandoned.</td>
</tr>
<tr>
<td>CAS-39881-G7R6</td>
<td>Recipient ODT SAR</td>
<td>Recipient treated with anti-virals following transplantation.</td>
</tr>
<tr>
<td>CAS-41430-Q0S7</td>
<td>Recipient ODT SAR</td>
<td>Discrepancy in testing results discovered post transplantation.</td>
</tr>
</tbody>
</table>

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Human error led to accidental damage to a body.

Lack of staff availability led to deterioration of the deceased.

Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence
<table>
<thead>
<tr>
<th>Case Number</th>
<th>Description</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-37976-Y1V7</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Mortuary reached capacity.</td>
</tr>
<tr>
<td>CAS-35298-G6T1</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error resulted in mix up of tissue.</td>
</tr>
<tr>
<td>CAS-39940-F0V2</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error led to loss of patient property.</td>
</tr>
<tr>
<td>CAS-40558-T8R7</td>
<td>Discovery of an organ or tissue following Post-mortem examination and release of body</td>
<td>Human error led to loss of tissue traceability.</td>
</tr>
<tr>
<td>CAS-40190-C3H5</td>
<td>Inadvertent disposal or retention of an organ against the express wishes of the family</td>
<td>Administrative error led to inadvertent retention of blocks and slides.</td>
</tr>
<tr>
<td>CAS-41030-Z7K0</td>
<td>Loss of an organ</td>
<td>Human error lead to loss of part of an organ.</td>
</tr>
<tr>
<td>CAS-40458-X2F6</td>
<td>Major equipment failure</td>
<td>Fridge failure resulted in transfer of bodies to another HTA-licensed establishment.</td>
</tr>
<tr>
<td>CAS-40441-C6K2</td>
<td>Major equipment failure</td>
<td>Equipment failure of extraction fan in PM room.</td>
</tr>
<tr>
<td>CAS-41774-J8S0</td>
<td>Major equipment failure</td>
<td>Hoist failure due to flat battery.</td>
</tr>
<tr>
<td>CAS-38191-X8M0</td>
<td>Post-mortem examination of the wrong body</td>
<td>Due to an identification error, a PM examination was started on the wrong body.</td>
</tr>
<tr>
<td>CAS-40113-M7G2</td>
<td>Post-mortem examination of the wrong body</td>
<td>Due to communication errors, a PM examination was started on the wrong body.</td>
</tr>
<tr>
<td>CAS-40092-M4L0</td>
<td>Release of the wrong body</td>
<td>Procedural error led to the short term release of the wrong body.</td>
</tr>
<tr>
<td>CAS-38689-W4M6</td>
<td>Release of the wrong body</td>
<td>Procedural error led to the short term release of the wrong body.</td>
</tr>
<tr>
<td>CAS-35675-S6D8</td>
<td>Release of the wrong body</td>
<td>Procedural error led to the short term release of the wrong body.</td>
</tr>
<tr>
<td>CAS-39858-W7Y0</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Removal of tissue biopsies from a body without correct consent form.</td>
</tr>
<tr>
<td>CAS-39427-Z7Y9</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-39642-C2W1</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-38359-B0V4</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Description</td>
<td>Additional Information</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-39798-W9P7</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-39108-V6M2</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-39347-M8H8</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
<tr>
<td>CAS-37753-N0J4</td>
<td>Viewing of the wrong body</td>
<td>Human error led to the viewing of the wrong body.</td>
</tr>
</tbody>
</table>
### Authority Report
**Development – Quarter Three 2017/18**

<table>
<thead>
<tr>
<th>Date</th>
<th>8 February 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Agenda Item</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>Paper Reference</strong></td>
<td>HTA (04/18)</td>
</tr>
<tr>
<td><strong>Author</strong></td>
<td>Hazel Lofty</td>
</tr>
<tr>
<td><strong>Protective Marking</strong></td>
<td>OFFICIAL</td>
</tr>
<tr>
<td><strong>Author Contact</strong></td>
<td><a href="mailto:hazel.lofty@hta.gov.uk">hazel.lofty@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

#### Strategic objectives (Development)
- To reduce regulatory burden where risks to public confidence are lowest
- To make it clearer how to achieve compliance with new and existing regulatory requirements
- To make continuous improvements to our systems and processes to minimise duplicated effort
- To take opportunities to better inform and involve the public

#### Relevant KPIs (marked as red, amber, green, black or blue)
- Deliver a project to implement EU Directives on Coding and Import
- Deliver a licensed establishment relationships programme as per plan specification
- Assessment of Risk in the Human Application sector and update of processes to reflect this

#### Related Strategic Risks (marked as red, amber or green)
1. Failure to regulate appropriately
2. Failure to manage an incident
4. Failure to utilise our capabilities effectively

(See paper HTA (02/18) Annex A for detailed information)*

*Note: Based on the Strategic Register last updated January 2018 to reflect the latest scoring and reformatting of the register.*
Purpose of paper

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

2. To provide a source of assurance on the development activities of the HTA.

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 25 January 2018.

Action required

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

Directors’ summary

5. The Regulations to implement the European Union (EU) Coding and Import Directives were laid before Parliament in December 2017. Subject to Parliamentary debate, the Regulations will come into force on 1 April 2018. Resources from the development and human application teams have therefore been directed towards re-establishing this project, with a particular focus on communications with Human Application establishments and internal staff training to ensure we are ready to answer enquiries and prepare to receive import licence renewals.

6. A new project team has been put in place to oversee the programme of work centred on relationships with licensed establishments. The team has met to consider progress against the initial programme plan, emerging priorities and future work. Inevitably, there have been delays to some elements due to resource constraints and more notably the requirements of the Department of Health and Social Care’s (DHSC) digital spend control process, on which further development of the online forum is contingent. However, steady progress is being made and the process has yielded valuable stakeholder insight that will inform the programme of work going forward.

7. With HA resources primarily dedicated to implementing the Coding and Import Directives, substantive work on the HA risk project work remains on hold. Information on Third Party Agreements is being collected, and the implementation work remains a priority for the 2018/19 business year.
Project updates

Core 2017/18 projects

8. The three projects below were considered core during 2017/18.

EU Coding and Import Directives implementation

9. The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018, which transpose both EU Directives, were laid before Parliament in December 2017. Subject to parliamentary debate, these regulations will come into force on 1 April 2018.

10. Subsector specific guidance has been developed which establishments can use to help prepare for implementation. This guidance was updated following feedback from the DHSC’s consultation on the draft Regulations and in response to enquiries from stakeholders.

11. Any establishment that is licensed for import will need to submit an application demonstrating how it will meet the requirements of the Import Directive, including details of their arrangements with suppliers. These will need to be assessed, and an updated licence certificate issued, by 1 April 2018 in order for them to continue importing. Establishments will be able to submit their applications via the HTA portal throughout February. Our intention is to assign a portfolio of establishments to each RM involved in order to offer as much support as we can due to the limited timetable.

12. Other work to be completed before the Regulations come into force includes revision of the Directions made for the purpose of securing adherence to the standards required under the EU Tissues and Cells Directives, updating standard licence conditions, updates to internal governance documents, finalising changes to IT systems and staff training.

Licensed establishment relationship programme

13. As reported at the last Authority meeting, a new project team has been convened following recent staff changes. The project team is now formed of four new members, including a Regulation Manager, with Authority oversight from two Members.

14. Feedback on the improved search functionality for inspection reports on the HTA website has shown that the new function has been well received by users.
15. Operational activity has also been focussed on improving email communications by cleaning up our mailing lists, ensuring that ‘hard-bounced’ emails from any key contacts are followed up and ensuring our emails are not filtered or treated as spam.

16. During quarter three, we conducted a survey of public and professional stakeholders on how they would like to interact with the HTA. The response rate was very positive and we will be able to use the feedback from professional stakeholders to steer the direction for new or improved ways of engaging with establishments, including development of the online forum. The next stage of this work is to develop user journeys, which will be carried out via our licensed establishment engagement panel, which was formed under this programme of work.

17. During quarter three we also finalised compliance updates from all establishments licensed in the post mortem, research, anatomy, public display and organ donation and transplantation sectors. We followed up with any establishment who had not submitted their information by the deadline to ensure that a completed submission was received. As part of this work, we also asked establishments to verify DI contact details and information.

18. The compliance updates highlighted an issue with the lack of a DI role in the ODT sector. Each clinical area has a named contact, however we are not always made aware when a contact changes. Further work is planned to address this via direct communications and during onsite audits.

19. The next phase of the programme is to:
   - Produce and deliver online tests on the three main pieces of HTA legislation (HT Act, Q&S Regulations and ODT Regulations). Draft questions for the tests have been developed and are being reviewed by the project team.
   - Build a repository of HTA training resources and scope the possibility of offering more substantive online training.
   - Continue to monitor how licensed establishments currently interact with the HTA by evaluating our existing methods and platforms of communication. This will include:
     - monitoring email and newsletter open rates;
     - ensuring we have a robust system in place to keep stakeholder contact details up to date; and
     - monitoring traffic on the HTA website.
   - Scope the possibility of organising sector-specific networking events or workshops for DIs, and explore further opportunities for providing training in partnership with other organisations, e.g. in the PM sector we support training
provided by the Association of Anatomical Pathology Technicians and are also exploring a programme of training in partnership with RCPPath.

- Consider, and if deemed necessary, undertake a review of establishments who do not currently engage with the HTA to see if there are other means through which we need to reach out to establishments.

**Assessment of risk in the human application sector**

20. This project delivered a series of recommendations for the future regulation of the HA sector, considering inspections, third party agreements (TPA) and preparation process dossiers.

21. These recommendations were agreed by the project board in quarter three. Human Application resources are currently deployed in implementation of the Import and Coding Directives, therefore implementation will be a priority project on the 2018/19 business plan.

22. In the interim, we will gather information relating to third party agreements (TPAs) with our routine annual activity data collection from the human application sector. This information will be used to prioritise the ongoing work on TPAs.

**Additional 2017/18 projects**

23. In quarter three of 2017/18, the following projects were considered to be of importance.

**Enquiries Project**

24. The enquiries project seeks to implement a range of improvement work relating to how the HTA handles enquiries. This work encompasses, and expands up, the recommendations from the internal audit on enquiries.

25. The project comprises three workstreams: 1. Systems (e.g. CRM, Skype, Portal etc...) 2. Process (how enquiries are received and their journey to completion) 3. Information. Recommendations from the audit are mapped against these workstreams, and form part of the detailed actions of the project.

26. This work will be completed between January and March 2018, with some follow up actions and/or future recommendations captured where appropriate.
Codes and Standards implementation review

27. Members will recall that the Codes and Standards were reviewed during 2015, laid before Parliament in 2016 and publicly launched in April 2017. In May 2017, a project implementation review was commissioned to determine whether the Codes and Standards Implementation project met the following aims and objectives:

- ensure that internal systems to reflect the new Codes and Standards;
- Regulation Managers are adequately trained to regulate against the revised codes and standards; and
- to provide guidance for Designated Individuals and licensed establishments on the new requirements and how to comply with them.

28. The findings of the review were largely positive and were based on round table discussions at an all staff away day in September 2017, an external stakeholder survey, which ran during October 2017 and a more recent survey of the project team.

29. The key lessons to emerge from the review concern the need for:

- conducting a comprehensive impact assessment at the start of such projects along with the better alignment of the competing demands of projects within the HTA continuous business planning process;
- greater follow through in terms of the ongoing awareness and preparation of staff and stakeholders during the implementation stages of projects; and
- the systematic capture of any statutory requirements during the project scoping phase of future projects.

30. The Stakeholder and Fees Group was provided with an interim update on the findings of the review at its meeting on 10 October 2017. The final report was presented to HTAMG in January and will be presented to the Stakeholder and Fees group at its next meeting on 9 May 2018.

Horizon scanning

31. The aim of this project is to formalise the current horizon scanning arrangements to provide organisational oversight of:

- the information we collect;
- sources of information;
- key internal and external contacts for information gathering; and
- gaps or overlaps in current horizon scanning activities.
32. Members will recall that a horizon scanning map has been developed to summarise the information sources the HTA currently has access to. The map details the different sources along with the team and individuals who have responsibility for managing them.

33. Following the mapping exercise, we are working to prioritise and assess the relative importance of each information source, distinguishing between high and low impact. The next phase will be to identify where we need to adapt working practices to more routinely embed horizon scanning capabilities into our organisational processes, for example we have recently added ‘Horizon scanning’ as a standing agenda item for both HWG and TAG.

34. We will also identify the assurances we have in place that core horizon scanning activities are taking place.

Review of the HTA advisory groups

35. In quarter three we carried out a survey of TAG members. The outcomes were largely positive:
   - Everyone agrees that the Group’s objectives are right and twice yearly meetings is about the right level of frequency;
   - There is interest in expanding the membership of the group to include lay members / members representing the field of deceased organ donation;
   - It was suggested that horizon scanning should be a standard agenda item.

36. The Head of Regulation for the ODT sector and the Chair of TAG will consider and review the suggestions made.

37. The Terms of Reference for Advisory Groups have been updated to reflect recent changes. A copy of the changes are included as Annex B to this paper. Members are asked to provide comment and otherwise approve the changes.

Development of a safety KPI

38. Building on the initial data analysis that was presented to the Authority in October 2017, work has been undertaken in quarter three to analyse inspection outcomes in the 2017/18 business year along with a cross-check of compliance information and HTARI reports in the post mortem sector.

39. This information will be included in the final report to the Authority in summer 2018.
Sustainability of the Independent Assessors framework and IA reaccreditation

40. This project aims to explore the opportunities available to us to strengthen or formalise arrangements, ensure the system is fit for purpose in the future and consider a move to continuous accreditation of IAs.

41. Members will be aware that the first phase of the project was a comprehensive survey of key stakeholders, including Independent Assessors. In total, 55 responses were received from IAs and 29 from Living Donor Coordinators.

42. Analysis of this data is taking place, which will inform next steps. Options and recommendations will be produced by the end of March 2018, and will be discussed in more detail at the Transplantation Advisory Group meeting on 23 May 2018. Implementation of any changes will take place during the 2018/19 business year.

Undertake Disclosure and Barring Service checks for Accredited Assessors

43. In 2016, work was completed to ensure that all IAs had enhanced DBS checks (or equivalent) in place. Members will recall that we have decided to implement the same checks and requirements for Accredited Assessors.

44. So far:

- thirty have completed the checks;
- ten have started the application, but have not yet completed the form;
- three have completed the application and are waiting to receive the certificate;
- two already have valid checks and are due to send certificates to the HTA;
- four are on maternity or sick leave and will complete the checks on their return. These four individuals are “inactive” on our system and therefore cannot undertake AA interviews.

45. This piece of work has taken longer than expected but significant progress continues to be made. Any assessors who do not complete the checks by the end of the business year will not be reaccredited. We anticipate however, this number to be very small.

46. The Guidance to Accredited Assessors and transplant teams has been amended and published to reflect the new requirements.

Collection of compliance updates from all sectors

47. Members will recall that in order to support our system of continuous licensing, every licensed establishment (other than those in human application) is required to provide us with a biennial update of licensing information and to complete a concise, sector-
specific questionnaire focused on risk and compliance with our standards. This helps us to maintain oversight of the sectors we regulate and guide our regulatory approach to each sector.

48. Compliance update submissions were received via the HTA portal from 31 August to 2 October 2017. All late submissions were followed up and we have now received compliance updates from all establishments.

49. The data has been collated, scored and circulated to the individual sector teams for further, more detailed, analysis. This data will be used to inform scheduling of site visit inspections for the 2018/19 business year.

**Development KPI narrative**

**Performance against 2017/18 KPIs**

50. All Development KPIs for Quarter three were within target or tolerance with the exception of KPI:7 – to deliver a project to implement EU Directives on Coding and Import, which is marked as red.

51. KPI:8 was marked as amber during December to reflect delays incurred due to staff turnover and delivery of the online forum. A revised programme plan will be provided to HTAMG in February. The programme remains within tolerance.

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

<table>
<thead>
<tr>
<th>Project</th>
<th>Brief description</th>
<th>Start date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Implementation of HA risk findings</td>
<td>Tbc subject to business plan approval</td>
</tr>
<tr>
<td>Development</td>
<td>Implementation of recommendations from IA sustainability project</td>
<td>Tbc subject to business plan approval</td>
</tr>
</tbody>
</table>
Annex A

Terms of Reference for Advisory Groups

Histopathology Working Group
Transplant Advisory Group
Stakeholder Group

Reference number: HTA-TOR-003
Version: xx
Owner: Strategy and Quality Directorate
Date approved:
Author(s): Amy Gelsthorpe-Hill
Next review date:
Approved by: Authority Members
Distribution: Internal and external

Background

1. The Human Tissue Authority (HTA) has established the Histopathology Working Group, the Transplant Advisory Group and the Stakeholder Group (the Groups) to maintain a positive and long-lasting impact on the services we regulate and ensure the safe and ethical use of human tissue.

2. The Groups will work in an advisory, not decision-making, capacity.

3. The Groups will not replace any of our existing mechanisms for formal consultation with other organisations, but will contribute to our thinking on work across the areas we regulate and the work we are assigned by the DHSC.

4. The Groups share common terms of reference in relation to their governance and recruitment, which are outlined in this document.

5. The Groups have differing terms of reference in relation to their constitutions, duties, functions and membership, which are outlined towards the end of this document.

Recruitment

6. Authority Members will be appointed to Groups by the Authority Chair.

7. Groups will be chaired by an Authority Member, who is not the Authority Chair and who preferably has relevant experience and expertise. Recruitment of the Chairs and Authority Members to each Group will be undertaken through ‘expressions of interest’ with a personal statement in application. These expressions will be reviewed by the Senior Management Team (SMT) with advice from the HTA Head(s) of function who support(s) the Group and provided to the Authority Chair for consideration.
8. The membership of individuals will be for a maximum term of three years, in line with the terms of Authority Members. It should be noted that Authority Members may be reappointed in accordance with the HTA’s business needs.

9. Professional bodies will identify individuals to represent them on the Histopathology Working Group and the Transplant Advisory Group. Further details of this can be found in the Histopathology Working Group and Transplant Advisory Group sections later in this document.

10. Groups may make appointments from additional organisations to the ones listed in accordance with business need.

11. Group members who are appointed by professional bodies will hold continuous membership, with a review of the membership of that job role taking place every three years.

**Member responsibilities**

12. Group members will be expected to provide apologies to the Secretary in advance of the meeting if they are not able to attend.

13. Group members must ensure that the existence and nature of any personal or material interest is disclosed before the discussion of a matter relevant to that interest, so to ensure the HTA is aware of an interest when considering any advice the member provides on the matter.

14. Members will be required to provide comments on the accuracy of minutes by email within the timeframe set by the Chair. This will ensure the key areas of discussion and action points are captured accurately.

**Frequency of meetings**

15. The Groups will each meet twice a year; they may also meet on an ad-hoc basis, if required.

16. Where necessary, members may be contacted outside of meetings to provide advice as and when it is needed. They may also be contacted to provide a paper, comment on a paper or review progress against agreed actions.

17. The format, frequency and outputs of the meetings will be reviewed annually by group members to ensure that the Groups are being effective in meeting their objectives.

**Attendance at meetings**

18. The quorum for each Group will be five, including the following members from each Group:

   a) Histopathology Working Group: either a member of the Senior Management Team or Head of Regulation with responsibility for the Post Mortem (PM) sector, one Authority
Member and two external representatives, one of whom must be a representative from the Royal College of Pathologists (RCPath);

b) Transplant Advisory Group: a member of the Senior Management team, two Authority Members and two external representatives;
c) Stakeholder Group: the Group Chair, a relevant HTA staff member and three external representatives.

19. Other HTA staff may attend Group meetings, with the agreement of the relevant Group Chair, to observe, present information or hear views. Their attendance may be limited to specific agenda items at the discretion of the Group Chair.

20. An observer from the DHSC shall be invited to attend Stakeholder Group meetings.

21. If it is deemed appropriate for other observers to attend meetings, they should be informed by the Group Chair that the views expressed by Groups members are not necessarily the views of the HTA and; that the Groups work in an advisory, not decision-making, capacity.

Right to expert advice

22. The Groups may, at the discretion of their Chairs, secure the attendance of any external advisors with relevant experience and expertise in order to discharge their responsibilities.

Reviewing effectiveness

23. The Groups will each draw on the National Audit Office’s self-assessment checklist for Audit Committees, as appropriate, in order to undertake annual reviews of their own effectiveness and agree actions for improvement. Each Group will report the results of the review to the Authority.

Reporting to the Authority

24. A verbal summary of the issues discussed at each meeting will be reported at the following Authority meeting by an Authority Member who is a member of the respective Group. The Member who will be responsible for providing the update will be agreed at each Group meeting and an ‘Advisory Group update’ will be a standing item on all standard Authority meeting agendas.

Communication

25. The Group Secretaries will be responsible for ensuring that a short summary of the issues discussed at each meeting is written for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and sent to the Head of Communications for publication.

26. The Secretariat will be responsible for ensuring any issue relating to the work of a specific Head of function is reported to that Head within five working days of the meeting.
Secretariat responsibilities

27. Group Chairs will assume responsibility for ensuring all agreed actions are completed.

28. The following HTA staff members will be appointed as Secretaries:

   a) Histopathology Working Group: a Regulation Manager with experience in the Post Mortem sector;
   b) Transplant Advisory Group: the Living Donation Officer;
   c) Stakeholder Group: the Stakeholder Engagement Manager.

29. Each Group Secretary will assume responsibility for the following tasks:

   a) inviting members to meetings;
   b) booking meeting venues;
   c) collating papers to be considered at meetings;
   d) liaising with the Chair to create agendas, ensuring that they are distributed with the minutes from the last meeting and any meeting papers at least one week before each meeting;
   e) taking minutes and recording action points from each meeting;
   f) ensuring minutes are circulated as soon as possible, at least within ten days of the meeting;
   g) approval of meeting minutes by the Group Chair prior to them being published on the HTA website, which will happen no later than two months after the meeting.

30. Minutes will be approved by the relevant Group Chair prior to being published on the HTA website. The Secretary will be responsible for ensuring that minutes are published on the website no later than two months after each meeting.

Review

31. This document will be reviewed by the Governance and Quality Manager and Authority Members every two years, with comment from the HTA’s Senior Management Team and the respective Groups.

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Comments</th>
<th>Reviewed by</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.0</td>
<td>17 March 2015</td>
<td>New Terms of Reference drafted to update and amalgamate terms for all Groups.</td>
<td>Amy Gelsthorpe-Hill</td>
<td>Authority Members</td>
</tr>
<tr>
<td>xx</td>
<td>February 2017</td>
<td>Updated to reflect changes following review of Advisory Groups</td>
<td>Hazel Lofty</td>
<td></td>
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</table>
Histopathology Working Group

Constitution

32. The HTA has established the Histopathology Working Group (HWG) to maintain a positive and long-lasting impact on the delivery of post mortem services, working with the sector to help drive up standards. Consultation with the HWG helps ensure that advice provided by the HTA remains current and in line with professional guidance.

33. In addition, the HWG considers on an on-going basis issues facing post mortem sector establishments, in order to inform the continued development of HTA regulatory policy affecting the sector and its overlap with the research sector.

Duties and functions

34. The HWG 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 Pathologists (RCPath) Death Investigation Group;
d) to report back to the Authority on key issues as necessary.

Objectives

35. The objectives of the HWG are to:

a) identify areas where advice and guidance is needed by the sector (including organisations that do not fall within our regulatory remit, for examples coroners and the police) and how this may be provided most effectively, such as through the development of policy or through other communication channels;
b) discuss issues resulting from implementation of the legislation or difficulties experienced by the sector and provide guidance on possible solutions or avenues of approach;
c) consider other legislation, current and future, and identify areas of overlap and disparity with the Human Tissue Act 2004;
d) take a strategic approach to unexpected incidents or events and approve the content of regulatory alerts relating to the sector;
e) perform horizon scanning for potential future changes and developments in the sector which might affect the HTA’s regulation;
f) work with external stakeholders on specific topic areas to achieve identified outcomes.

Membership

36. The HWG will be chaired by an Authority Member, appointed by the HTA Chair, and with support from the Head of Regulation with strategic lead for the post mortem sector.
37. Other members of the HWG will be appointed by the following stakeholder organisations, either by the appointment of individuals or specific job roles:

a) Royal College of Pathologists (RCP);  
b) British Medical Association’s (BMA’s) Central Consultants and Specialists Committee (CCSC) Pathology Subcommittee;  
c) Association of Anatomical Pathology Technology (AAPT);  
d) Home Office;  
e) Forensic Science Regulator;  
f) Coroners’ Society;  
g) Institute of Biomedical Science (IBMS);  
h) Ministry of Justice (on occasion);

38. The HTA will appoint the following members to the HWG:

a) A minimum of two Authority Members: one lay and one professional;  
b) the Director of Regulation or Director of Policy, Strategy and Communication;  
c) the Head of Regulation with strategic lead for the Post Mortem sector;  
d) a representation from the Communications directorate.
Transplant Advisory Group

Constitution

39. 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 NHS Blood and Transplant (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.

Duties and functions

40. The TAG has three core functions:

   a) to maintain strategic oversight of living organ donation and to check and challenge the HTA’s decision-making processes;
   b) to provide a forum for debate on sector-specific issues to inform policy decisions and identify work streams / projects;
   c) to report back to the Authority on key issues as necessary.

Objectives

41. The objectives of the TAG are to:

   a) identify areas where advice and guidance is needed by the sector and how this may be provided most effectively, for example through the development of policy or guidance or through other communication channels;
   b) discuss arising policy or legislative issues and difficulties experienced by the sector with the aim of providing suitable guidance or solutions;
   c) work with transplant units on specific subject areas to achieve identified outcomes, such as new programmes in living organ donation (novel organs);
   d) provide informal soundings and advice on emerging policy issues or novel transplants.

Membership

42. The TAG will be chaired by a member of the Authority, appointed by the HTA Chair and supported by the Head of Regulation with strategic lead for the organ donation and transplantation sector.

43. Other members of the TAG will be appointed by the following stakeholder organisations, either by the appointment of individuals or specific job roles:

   a) representatives from NHSBT;
b) a Living Donor Coordinator;
c) clinical representation from the transplant community, to include both a Liver Specialist and a Kidney Specialist.

44. The HTA will appoint the following members to the Group:

   a) the Director of Regulation or Director of Policy Strategy and Communications;
   b) the Head of Regulation with strategic lead for the Organ Donation and Transplantation sector;
   c) the Living Donation Manager;
   d) A minimum of two Authority Members: one lay, one professional;
   e) a representative from the Communications directorate.
Stakeholder Group

Constitution

45. The HTA has established the Stakeholder 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.

46. The Stakeholder Group has been established to ensure the HTA continues to improve transparency and accountability and maintain effective working relationships with establishments we license.

47. Stakeholder Group members will 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.

Duties and functions

48. The Stakeholder Group will have three core functions:

   a) to provide an ongoing channel of communication with stakeholders;
   b) to provide a forum for regular discussion of regulatory issues;
   c) to consider fees proposals annually.

49. The Head of Communications will ensure that advice, which is specifically related to living organ donation or the post mortem sector, will be referred to TAG and HWG respectively, as it is deemed appropriate.

Objectives

50. The Stakeholder Group will consider regulatory issues across all licensed sectors to inform the continued development of HTA regulation and fee setting.

51. Achieving best value for money through a robust fee-setting process is essential to ensure the costs of regulation are both proportionate and fair and that the regulated sector can operate efficiently and competitively. The Authority approves fees in November of the year before they are charged and new fee levels are announced in December. Fees are charged for the year from April to March, with invoices issued in April or September depending on the sector. The Stakeholder Group shall review fee proposals in October each year, to inform the Authority’s consideration.

Membership

52. Recruitment of an Authority Member to the position of Stakeholder Group Chair will be undertaken through ‘expressions of interest’ with a personal statement in application, in accordance with paragraph six of this document. These will be reviewed by SMT, with recommendations put to the Authority Chair.
53. The Stakeholder Group will comprise of up to 13 representatives from the sectors licensed by the HTA, members of the public and other stakeholders.

54. The HTA will appoint the following staff members to the Stakeholder Group:

   a) the Chief Executive;
   b) the Director of Regulation or Director of Policy, Strategy and Communication
   c) the Director of Resources;
   d) the Head of Communications.
### Authority Report
#### Deployment – Quarter Three 2017/18

<table>
<thead>
<tr>
<th>Date</th>
<th>8 February 2018</th>
<th>Paper Reference</th>
<th>HTA (05/18)</th>
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<tbody>
<tr>
<td>Agenda Item</td>
<td>9</td>
<td>Author</td>
<td>Richard Sydee</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<td>Author Contact</td>
<td><a href="mailto:Richard.Sydee@hta.gov.uk">Richard.Sydee@hta.gov.uk</a></td>
</tr>
</tbody>
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### Strategic objectives (Deployment)

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

<table>
<thead>
<tr>
<th>Relevant KPIs (marked as red, amber, green, black or blue)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Reduce attrition rates through improved selection and targeted retention measures to retain staff</td>
</tr>
<tr>
<td>• Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff</td>
</tr>
<tr>
<td>• Lead and advise on best recruitment procedures to maintain organisational capacity and capability</td>
</tr>
<tr>
<td>• Manage all development options offered to staff and evaluate courses to ensure quality delivery and learning effectiveness</td>
</tr>
<tr>
<td>• Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees</td>
</tr>
<tr>
<td>• Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees</td>
</tr>
</tbody>
</table>

### Related Strategic Risks (marked as red, amber or green)

2 Failure to manage an incident
4 Failure to utilise our capabilities effectively
5 Insufficient, or ineffective management of financial resources

(See paper HTA (02/18) Annex A for detailed information)*

*Note: Based on the Strategic Register last updated January 2018 to reflect the latest scoring and reformatting or the register.
Purpose of paper

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

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

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 25 January 2018.

Action required

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

Director’s summary

5. In quarter three, risk continues to be posed by the departure of a number of senior staff. This has been partly mitigated by the interim appointment of two experienced internal applicants to the Director posts, and the subsequent appointment of Regulation Managers to fill the resulting vacancies at Head level on an interim basis.

6. This level of change and uncertainty has proved unsettling for staff, although there are indications that these are beginning to settle since the start of the year. An update on the plans for the Director roles and for the organisational structure more generally will be presented at the meeting.

7. There are continuing indications of difficulty in recruiting staff from outside the HTA to vacant posts. Mitigations for this risk are being worked up as part of the next iteration of the People Strategy.

8. Our forecast position through to the end of the 2017/18 financial year is now to generate a small surplus of £30k, the result of continued financial control and some unfilled vacancies over the last quarter.

People

People Strategy

9. The activities on the road map for the current people strategy have almost been delivered, although work on reviewing the competency framework has been deferred.
Good progress has been made on the assessment of the need for a senior RM role. Work to revise the People Strategy, to support the revised organisational Strategy, will be started in quarter one of the new business year.

Staff Survey

10. The 2017 staff survey was undertaken during November/December 2017 in order to provide an opportunity for staff to feedback on their experiences in working for the HTA, and to highlight issues they feel should be addressed in the future.

11. Overall, the results are positive relative to other similar bodies in the public sector, and there is a lot to be proud of in the current operating environment and in light of the changes that the HTA was experiencing at the time the survey was launched. At the same time, while still above performance benchmarks, there has been a deterioration across a wide range of indicators, and halting this decline will be a key area for action.

12. Given the level of organisational change we are experiencing, SMT has agreed that the results provide a good opportunity for the whole of the management team to agree on the priorities for action during 2018/19 and to use this as the basis for our development as a team over the coming year.

13. Members will be provided with an overview of the results by way of a presentation at the February meeting. The Authority should also note that the Audit and Risk Assurance Committee has been provided with the full survey results, including the verbatim comments, in order to inform its deep dive on HTA management and culture.
Finance

Financial position for end of Q3 2017/18

14. The table below details the summarised financial position as at 31 December 2017 (quarter 3 of the 2017/18 year) and our forecast for the year ending 31 March 2018. There is an underspend against budgeted expenditure of £117k and more income than originally profiled by £122k. The latter is due to the early draw-down of our Grant in aid (GIA) which is £150k.

Table One: Income and Expenditure summary

Human Tissue Authority

Summary - Income & Expenditure

For the Nine Months Ending 31 December 2017

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>OUTTURN</th>
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<tbody>
<tr>
<td></td>
<td>Actuals £</td>
<td>Budget £</td>
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<tr>
<td><strong>INCOME &amp; EXPENDITURE SUMMARY</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(4,439,987)</td>
<td>(4,317,821)</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>3,371,291</td>
<td>3,486,476</td>
</tr>
<tr>
<td><strong>Net (surplus)/deficit of income over expenditure</strong></td>
<td>(1,068,696)</td>
<td>(831,345)</td>
</tr>
</tbody>
</table>

15. The components of our income and expenditure are further explained in Tables 2 and 3.

16. The second tranche of our grant in aid has been drawn down and is higher than initially profiled; however, we are still on course to fully draw down our cash allocation by the end of February

17. Licence fee income, including application fees, are below budget by £55k. All of our existing licence fees have been billed, with the remaining sectors invoiced in September. There has been some additional income in the form of application fees in December totalling £8k. The shortfalls shown in table 2 are not expected to increase.
Table Two: Income Summary

Human Tissue Authority

Member Income Summary

For the Nine Months Ending 31

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>/outturn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
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<tr>
<td>Grant In Aid</td>
<td>750,000</td>
<td>600,000</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>750,000</td>
<td>600,000</td>
</tr>
<tr>
<td>Licence Fees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Fees</td>
<td>33,103</td>
<td>48,200</td>
</tr>
<tr>
<td>Anatomy</td>
<td>88,675</td>
<td>88,850</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>1,050,913</td>
<td>1,061,950</td>
</tr>
<tr>
<td>Public Display</td>
<td>19,004</td>
<td>15,900</td>
</tr>
<tr>
<td>Research</td>
<td>592,817</td>
<td>587,350</td>
</tr>
<tr>
<td>Human application</td>
<td>1,256,202</td>
<td>1,291,900</td>
</tr>
<tr>
<td>ODT</td>
<td>246,700</td>
<td>248,000</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>3,287,414</td>
<td>3,342,150</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income (Rent)</td>
<td>232,603</td>
<td>231,910</td>
</tr>
<tr>
<td>Other income (Secondees)</td>
<td>40,006</td>
<td>27,761</td>
</tr>
<tr>
<td>Devolved Assemblies</td>
<td>129,964</td>
<td>116,000</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>402,573</td>
<td>375,671</td>
</tr>
<tr>
<td>Total Income</td>
<td>4,439,987</td>
<td>4,317,821</td>
</tr>
</tbody>
</table>

18. The surplus within secondee income is due to a secondment that was not budgeted for and will span this and the next financial year.

19. Table three provides a summary of expenditure as at 31 December 2017 for staff and non-staff costs.
Table Three: Summary Expenditure

Expenditure Summary

For the Nine Months Ending 31 December

<table>
<thead>
<tr>
<th>Budget</th>
<th>Year to Date</th>
<th>OUTTURN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals  £</td>
<td>Budget  £</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td>Travel &amp; Subsistence</td>
<td>2,168,052</td>
<td>2,256,321</td>
</tr>
<tr>
<td>Training/Recruitment</td>
<td>(24,298)</td>
<td></td>
</tr>
<tr>
<td>Post, Stationary, Printing</td>
<td>(7,289)</td>
<td></td>
</tr>
<tr>
<td>IT &amp; Telecoms</td>
<td>(12,280)</td>
<td></td>
</tr>
<tr>
<td>Accommodation</td>
<td>(30,953)</td>
<td></td>
</tr>
<tr>
<td>Legal &amp; Professional</td>
<td>20,151</td>
<td></td>
</tr>
<tr>
<td>Consultancy</td>
<td>10,672</td>
<td></td>
</tr>
<tr>
<td>Non cash</td>
<td>(7,000)</td>
<td></td>
</tr>
<tr>
<td>Small variances</td>
<td>(6,623)</td>
<td></td>
</tr>
</tbody>
</table>

20. Year to date there is an overall under spend against budget of £117k
   a. Staff costs are underspent by £88k which is the result of carrying a number
      of vacancies through the third quarter of this financial year
   b. There is an under spend on non-staff costs of £29k. Below are details of the
      material variances.

Table One: Expenditure variance

<table>
<thead>
<tr>
<th>Budget</th>
<th>£</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Travel &amp; Subsistence</td>
<td>28,570</td>
<td>Increased inspections and costs</td>
</tr>
<tr>
<td>Training/Recruitment</td>
<td>(24,298)</td>
<td>Mainly under spends in training</td>
</tr>
<tr>
<td>Post, Stationary, Printing</td>
<td>(7,289)</td>
<td>Reduction in stationary orders, re-negotiated photocopier contract</td>
</tr>
<tr>
<td>IT &amp; Telecoms</td>
<td>(12,280)</td>
<td>Reduced Licence subscription costs</td>
</tr>
<tr>
<td>Accommodation</td>
<td>(30,953)</td>
<td>Service charge/Rates budget profile error</td>
</tr>
<tr>
<td>Legal &amp; Professional</td>
<td>20,151</td>
<td>Legal and Audit fees higher than planned</td>
</tr>
<tr>
<td>Consultancy</td>
<td>10,672</td>
<td>Unplanned Consultancy costs</td>
</tr>
<tr>
<td>Non cash</td>
<td>(7,000)</td>
<td>Capital expenditure reduced</td>
</tr>
<tr>
<td>Small variances</td>
<td>(6,623)</td>
<td></td>
</tr>
</tbody>
</table>

Forecast outturn

21. For the full year, we are forecasting a surplus of £31k against the original budget deficit
    of £18k (as per Table One). The forecast assumes that the majority of recruitment costs
will be incurred by year end, although staff vacancies are unlikely to be filled until the start of the next financial year

22. The Department of Health and Social Care (DHSC) has indicated that it will fund the rent increase for 2017/18, as they did for 2016/17. This leaves only the VAT issue unresolved; although the Department has offered a solution but it is dependent on the other tenants of our building accepting this offer – in order that we can fully recover costs from the sub-tenancy agreement we have with NHS Resolution. At this time, the other tenants have not accepted the offer, the Department continues to discuss this matter with the Finance Directors of all organisations affected and it is hoped this matter will be resolved ahead of the year end.

Other key performance indicators

Debtors

23. As at 31 December 2017 our licence fee debtor balance is **£28k**. Of this balance, £19k relates to three establishments billed in September, two of which are NHS Trusts totalling with outstanding payments totalling £16k. In both cases there have been issues relating to the revocation of licences and the total amount payable by the Trusts. The latest correspondence with one of Trust has resolved the issues and payment is expected shortly, we remain in discussions with the second.

24. The remainder of the debts are made up of private organisations whose outstanding balances are relatively minor.

Financial risks

25. Financial risks are monitored on an ongoing basis. Below is the current key financial risk identified and the mitigating actions and controls taken to minimise it.

26. The financial risk in this summary feeds in to the five high-level strategic risks that SMT has identified and is managing. Strategic risk five – insufficient, or ineffective management of financial resources – is currently holds a RAG status **yellow** as we have faced challenging budget issues this financial year due to under recovery of fees at a more significant level than that in previous financial years. As at the end of quarter three, we are forecasting a small surplus by year end, which has reduced the likelihood of insufficient funds this financial year.
Table Four: Risks and mitigations

<table>
<thead>
<tr>
<th>Risk</th>
<th>Mitigating actions and controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>An overspend may lead to a lack of stakeholder confidence in HTA’s ability to manage resources effectively.</td>
<td>Monthly review of financial position; quarterly finance meetings to review deferrable activities</td>
</tr>
</tbody>
</table>

Business technology and working environment

Business technology

27. The CRM upgrade is continuing according to plan with no reported issues or concerns. We have consciously limited further development of the live system to essential or relatively simple initiatives to avoid complicating the upgrade process unnecessarily. We continue to review and assess HTA Wiki usage against its original stated purpose. We will consider the future of the Wiki in the IT strategy and business planning for the coming year.

Working environment

28. We have been conducting a review of potential replacement laptops and have provided various staff across the organisation with a variety of potential replacement devices, changing people and devices on a weekly basis and eliciting feedback on each change. The trial concluded on 26th January and we will now assess the feedback and present our analysis and recommendations to the SMT.

Deployment KPI narrative

Performance against 2017/18 KPIs

29. KPI:10 Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly) was marked as red, at 22% in December.

30. KPI:12 Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly) was marked as red, with six unfilled vacancies in December.

31. KPI 14 Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity was marked as amber. A small underspend is now projected at year end, however, the issue of VAT on rent is still unresolved.

32. All other Delivery KPIs for quarter one are within target or tolerance and marked as green.
Regulatory Futures

Purpose of paper

1. To provide the Authority with information about the Cabinet Office initiative on Regulatory Futures.

Decision-making to date

2. The HTA has provided information on its regulatory functions to the Department of Health and Social Care (DHSC). This will be fed into DHSC’s submission to the Cabinet Office.

Action required

3. Members are asked to note the contents of this paper.

Background

4. The Regulatory Futures Review was undertaken by a coalition of regulatory arm’s length bodies (ALB). They were commissioned by the Cabinet Office’s Public Bodies Reform team as the first of a series of “cluster” reviews of ALBs.

5. The Regulatory Futures Review arose from a view among regulators that significant improvements in operational efficiency could be found by sharing good practice between regulators and developing more collaborative working models, and that this would help achieve ambitious spending review targets
6. In the light of the report of the Regulatory Futures Review, Ministers collectively agreed that Departments should pursue opportunities for savings from regulated self-assurance and full cost recovery by regulators. Implementation is one of the Cabinet Office’s high priority projects.

Summary of Regulatory Futures

7. As per the key recommendation from the report, the Cabinet Office is primarily pursuing opportunities linked to three over-arching concepts. For each of the concepts, the applicability to the HTA is limited, in part because of the profile of licensed establishments within each sector.

8. The HTA licences around 500 establishments across six sectors. Each sector has a discrete set of licensing standards. The individual cohorts of establishments to which each concept of the initiative could be applied are minimal.

9. In addition, the HTA regulates a large number of public bodies (NHS Trusts, Other Health ALB, Museums, Medical schools and Research Universities).

10. In the private sector, we are keenly aware of the small margins that operators are working to in some of the sectors we regulate and the potential for further fee increases to become a barrier to entry for new organisations entering the bio and life sciences market.

Concept 1: Regulated Self-Assurance (RSA)

11. RSA is not a single techniques and is based on providing greater freedom for regulated businesses to self-assure either directly themselves or through the use of assurance bodies.

12. Where there is broad alignment between business goals and the objectives of regulation, regulated self-assurance involves the regulator validating business processes and relying on their results for regulatory purposes.

13. Examples of where RSA currently applies to the HTA include use of joint inspections (for example with United Kingdom Accreditation Service (UKAS)), joint working with other regulators and risk based inspection scheduling.

14. The HTA has provided some feedback to the Cabinet Office on its experience of RSA to date. In particular, the challenges were highlighted with respect to its application to a small and specialist regulator.
15. The HTA currently operates cost recovery through licence fees and there are limiting factors that apply to the HTA’s use of RSA.

- The time and resource required to establish such schemes is of limited benefit to a small cohort of establishments. For example, there are 15 establishments in the Post Mortem sector where some activities have been inspected by UKAS. Establishment uptake of the provision for a joint UKAS inspection has been low to date.

- Previous experience has demonstrated that fulfilling the legislative requirement for a biennial inspection within the human application (HA) sector does not lend itself to RSA. For example, where functions could be delegated/co-regulated and need to fit into other inspection schedules.

**Concept 2: Full Cost Recovery (FCR)**

16. FCR applies to regulators that receive voted money and is intended to eliminate taxpayer support.

17. The HTA currently receives voted money in the form of grant in aid (GIA) from DHSC. Other income sources include monies from devolved administrations, rent from sublet of office accommodation and outward secondment of HTA staff.

18. The HTA achieves cost recovery through fees charged to licensed establishments, but is unlikely to be able to achieve FCR.

19. There is a general provision on Part 3, paragraph 55 of the Human Tissue Act, which refers to money provided by Parliament in relation to expenditure incurred by the Secretary of State.

20. The work the HTA carries out around organ donation, explicitly Living Donation assessments, is performed on behalf of government rather than licence holders. This work is therefore not a chargeable regulatory function and has to be funded via GIA.

**Concept 3: Assured Advice**

21. The HTA does not currently provide assured advice.

22. The main reasons for this are that the HTA has powers to provide legal certainty by issuing legal directions. These specify how establishments should comply with legislation. Beyond this, the HTA has a statutory duty to provide
advice and guidance, which is tailored due to the bespoke and specialist nature of our regulation.

23. There is one limited area where the HTA provides advice that may go beyond our cost recovery processes and where assured advice could be considered. This currently arises approximately 10-20 times per year in the HA sector.

24. It applies where licensed establishments are required to submit a preparation process dossier before we will authorise their processing methods. Here, we provide technical advice that is tailored to an individual establishment’s circumstances. No charge is applied specifically to this advice, although we do recoup costs more widely via licence fees for processing.

25. We may also consider if there are future opportunities to provide assured advice in relation to licence applications.

Conclusions

26. The HTA already achieves cost recovery where possible and applies the principles of RSA. Further opportunities are limited due to the profile of our regulated sectors and the small cohorts involved.

27. It is recommended that future opportunities be explored where they have potential to reduce regulatory burden and are in keeping with the HTA’s regulatory model.

28. A watching brief will also be maintained over the initiative in order to highlight any wider reaching implications for the HTA. We have established contacts within the Cabinet Office who are keen to engage us in future developments.
HTA Strategy 2018 - 2021

Purpose of paper

1. To provide the Authority with a draft of the Strategic Plan for 2018 – 2021 for approval. This includes the draft Key Performance Indicators (KPIs) which the Authority and the Department of Health and Social Care (DHSC) will monitor during the coming business year.

Action required

2. The Authority is asked to provide comment the draft Strategic Plan. Members will be provided with a final draft of the plan for approval by correspondence prior to publication on 1 April 2018, pending appointment of the new Chair.

Background

3. The draft 2018 – 2021 Strategy document is included at Annex A to this paper. It describes our strategic approach and direction, key challenges and opportunities, our strategic objectives and how we will deploy our resources on the priority areas identified over the next three years.

4. At its away-day in October 2018, the Authority undertook a review of changes in its strategic environment. The review was based on a fundamental evaluation of the extent to which our current strategic approach protects public and professional confidence in the proper use, and quality and safety of, human tissues, cells and organs. A high level summary of the away day discussions is included at Annex B.
Our vision is to become a more sustainable, resilient and agile regulator by 2021.

5. The envisaged organisational transformation will be phased over the next three years. The first step in implementing the Strategy will be to develop a more detailed blueprint proposal, which will outline the changes we need to make to our People Strategy, Business Technology and Estates plans.

6. We are putting our staff at the heart of this Strategy – but they will need strong support from our business technology to be able to function efficiently and effectively. With our current lease expiring in 2021, there is also the opportunity to define our future accommodation needs.

7. We recognise that change is challenging – new ways of working need to be managed well. There needs to be a single culture of working according to shared values and respect for the team as a whole. We will use the ARAC deep dive to gauge where we are now, and where we need to get to, as well as the outcomes from the recent Staff Survey.

8. We are also cognisant of the impact delivering this change will have on available resources. Although successful delivery will ultimately make us more productive, the changes will need to be planned carefully and ruthless prioritisation will be necessary. We will use this as an opportunity to challenge what we do, and how we do it.

9. Planning and rolling out the changes will involve close liaison between the Authority, SMT and the wider HTA Management Group. Those responsible for estates and facilities, IT and HR functions will needs to work closely with the managers of teams undergoing the transition.

10. We will establish an inter-disciplinary programme team to manage the changes as a business transformation programme with representation from Authority members. The team will develop a plan detailing the costs, timescale and risks. We will use established tools, such as the Government's 'The Way We Work' guide to Smart Working, to plan and consider the best options for the HTA.

11. In particular we will:
   a. Take a proactive rather than a reactive approach to flexibility, seeking out benefits such as a wider pool for recruitment and improved staff retention, rather than waiting for individual staff requests;
   b. Put a greater emphasis on line management, which focuses on results rather than presence, and developing this as a core management competence; in this way we will build trust based relationships throughout the organisation;
c. Consider how we reduce the footprint of how we work, including both financial and environmental costs (e.g. taking more account of geographical location of inspection teams);
d. Become more adaptable to change, so the organisation can flex to meet the delivery and development priorities demanded of us; making better use of flexible resourcing, with project teams brought together for limited periods;
e. Embrace the concept of the office being the network rather than a physical location – the platforms and business technology infrastructure that allows us to communicate and do our work will be key to our success;
f. Focus on getting the job done quickly and well – empowering our staff as much as possible;
g. Evaluate the tasks within roles to see if better organisation of tasks can bring more scope for working more effectively;
h. Develop different ways of keeping in contact with staff, of assessing workloads and monitoring and measuring performance. Greater sharing of schedules, information and updates. Development of protocols about communication and reporting to maintain team cohesion;
i. Reserve physical meetings for important collaborative work such as training, brainstorming and decision-making. Routine meetings can be undertaken using audio, video or web conferencing;
j. Recognise that effective use of new technologies will be essential for success. We need to make the right technology choices including:
   i. Devices
   ii. Digital by default for our processes
   iii. Cloud storage and application hosting
   iv. Improved electronic document management and records management system
   v. Telephony
   vi. Conferencing technologies
   vii. Online collaboration and social networking technologies; shared virtual spaces
Executive Summary
This document sets out the strategy for the Human Tissue Authority (HTA). It describes our strategic approach and direction, key challenges and opportunities, our strategic objectives and how we will deploy our resources on the priority areas identified over the next three years.
Introduction from the Chair

TBC – confirm with new Chair

The HTA’s Strategy 2018 – 2021 establishes the Authority’s overarching strategy and objectives for the next three years – it sets out an ambitious vision:

*a more sustainable, resilient and agile regulator focussed on ensuring that public and professional confidence in the use of human tissue is maintained.*

This new strategy has been developed following a fundamental evaluation of the extent to which we achieve our overall aim of protecting public and professional confidence in the use of human tissue. It builds on the aims and achievements of the HTA Strategy: 2016-2019 and over a decade’s experience in regulating…
About the HTA

The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health and Social Care, established by the Human Tissue Act 2004.

Our aim is to ensure that public confidence in the proper use of human organs and tissue is maintained by ensuring compliance with the provisions of the Human Tissue Act 2004, and that tissues, cells and organs used in transplantation meet appropriate standards of quality and safety.

Our role:
- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the EU Tissues and Cells Directives;
- We license organisations involved in organ donation and transplantation as required by the EU Organ Donation Directive;
- We monitor and inspect or audit organisations to ensure they comply with the requirements of the legislation and our Codes of Practice;
- We use our powers to take regulatory action where we identify non-compliance;
- We approve living organ donations to ensure donors are protected from duress or coercion, and that no reward is given;
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit;
- We monitor developments relating to activities within our remit and advise Government on related issues.

Our remit:
- Removal, storage and use of human tissue and organs for a number of activities and scheduled purposes as set out in the Human Tissue Act 2004, such as post-mortem examination, anatomical examination, research, transplantation and public display;
- Procurement, testing, preservation, processing, storage, distribution, import and export of tissues and cells for use in patient treatment (human application);
- Donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of organs for transplantation.

Our remit under the Human Tissue Act 2004 extends to England, Wales and Northern Ireland; however, we also carry out some activities in relation to the approval of living organ donation on behalf of the Scottish Government. Our remit as the Competent Authority for the quality and safety of tissues, cells and organs used in transplantation extends to the whole of the UK.

We license approximately 860 premises across the six sectors that we regulate and publish standards and requirements that those working within the regulated fields must meet.
Whilst the HTA has an influential role in superintending compliance and promoting good practice, public confidence in the use of human tissue cannot be safeguarded by the HTA alone. Public confidence is also dependent on individuals and organisations undertaking activities within the HTA’s remit to act within the standards and requirements of the legislation.

Four guiding principles continue to drive our work and underpin our regulatory framework. They should be followed in dealing with human bodies, tissue and organs:

- **Consent** – and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.
- **Dignity** – is paramount in the treatment of human bodies and tissue.
- **Quality** – must underpin the management of human bodies and tissue.
- **Honesty and openness** – are the foundation of communications in matters pertaining to the use of human tissue and bodies.

Our values as an organisation in carrying out our role:

- **Expertise** – being responsive, providing specialist knowledge
- **Excellence** – focus on achieving exceptional results and inspiring others to do the same
- **Integrity** – be trustworthy, honest, fair and consistent
- **Respect** – have empathy and be impartial; value others’ expertise and experience
- **Transparency** – be open, collaborative and involve and communicate effectively.

In our previous strategy, we described our key activities as grouped within three themes:

- **Delivery** – how we achieve our strategic objectives today;
- **Development** – how we will improve in the future;
- **Deployment** – how we effectively use our people and resources.

This strategy continues to build on these themes, with a renewed focus on striving to be a more resilient, sustainable and agile organisation in order to meet the challenges ahead. More detail can be found in the Strategic Approach section of this document.
Strategic Review

In preparing this Strategy, the HTA has undertaken a fundamental evaluation of the extent to which our current strategic approach protects public and professional confidence in the proper use, and quality and safety of, human tissues, cells and organs. We based this evaluation on evidence and analysis from a variety of sources, including the views of those working in establishments we regulate, a new evaluation of public opinion, analysis of the data we hold and the views and opinions of HTA staff and Authority Members.

As a statutory body, our aim remains unchanged. As such, our review focussed on evaluating our future operating environment and whether our resources are optimally aligned to where the risks to achieving our aim are greatest.

An assessment of the evidence provides us with great reassurance that both the public and professionals think we are on the right track with our regulatory approach. However, the review identified a number of opportunities and challenges relating to our future operating environment that will require us to adapt as an organisation.

The pace of innovation in cell, tissue and organ based therapies, in life sciences research, and the use of imaging and artificial intelligence in pathology, all have the potential to impact hugely on the way the sectors we regulate work. Many of these developments were unanticipated when the legislation was framed, and we need to be realistic about the availability of resources for legislative change.

As one of the regulators operating in the field of life sciences, we are clear that effective regulation can make a positive contribution to patient outcomes and to economic growth. We need to be prepared to meet the ambitious plans set out by the Government through the Industrial Strategy, as well as potential changes to organ donation policy and the outcomes of UK’s exit from the European Union.

We recognise that our staff are our key asset – their skill and dedication lies at the heart of our organisation and therefore staff recruitment and retention contribute significantly to our strategic risk. As the regulator of six increasingly complex and diverse sectors, and with continued pressure to control our resources, we are acutely aware of the demands this can place on our staff.

This strategy is therefore focussed on the steps we needs to take over the next three years to be operating in a more sustainable way by 2021, building in greater resilience and agility in the face of increasing complexity and uncertainty in our external environment.

By sustainable, we mean taking a new approach to recruiting and retaining high quality staff and working in new ways to reduce the growing pressures on the staff we have.

By resilience, we mean adapting our operating model to retain staff for longer and forming strategic alliances with other organisations to put us in a better position to manage unexpected demands.
By **agility**, we mean providing a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells, burnishes our reputation as an expert regulator and actively supports the Industrial Strategy for Life Sciences.

In order to meet the challenges ahead we require a fresh focus on our:

**People** – recognising our staff as our key asset, widening the pool of candidates for recruitment and investing in training and development;

**Business Technology** – ensuring our systems are not reliant on location and making strategic choices about key business systems;

**Information and data** – meeting our obligations relating to data security and using information and data as a key strategic resource;

**Finance** – being clear about our fees aspirations and longer term planning to ensure continued financial viability.

Year 1 of this strategy represents a transition between the previous 3 year strategy and the new priorities. Our 2018/19 business plan will therefore reflect the trade-offs between current and emerging business needs.
Our Strategic Approach

Our strategic approach is based on right-touch regulation. This means being clear on the risks we are regulating, being proportionate and targeted in regulating those risks, taking into account the role of professional bodies and other regulators, and using the minimum necessary regulatory force to achieve compliance and improvement. Effective communication is also critical to our strategic approach to ensure that professionals can readily access advice and guidance from us, and that the public is clear on what they should expect from us and the areas we regulate. How we do this in our daily operation is described in the Delivery section of this Strategy.

The HTA has never been an organisation to stand still, and is continually looking for ways it can enhance public confidence, better target our regulation and adapt as an organisation. The Development section of the Strategy describes the renewed focus for our development goals during this strategic period to ensure sustainability, resilience and agility in addition to continuing our program of continuous improvement.

Neither Delivery or Development is possible without resources. The Deployment section of the Strategy describes how we lead, manage and develop the HTA’s people, how we raise and use our finances and our plans for accommodation and other key assets.

Our objectives are therefore grouped into three themes:

Delivery – To deliver the right mix of operational activity to maintain public and professional confidence

Development – To make the right investment to continuously improve delivery and deployment

Deployment – To make the most effective use of people and resources in pursuit of our goals

All of these aspects will require a careful balance to make the most of our limited resources and ensure success in delivering our overall aim.
Delivery

Deliver the right mix of operational activity to maintain public and professional confidence, and ensure quality and safety, in the use of human tissue

Our regulatory approach aims to be right-touch and in line with the principles of better regulation and the Regulators’ Code. This means that we primarily focus our regulation and resources on establishments that carry out activities that involve an inherently greater risk if standards are not maintained.

We employ a range of regulatory tools in order to ensure compliance with the legislative requirements, including licensing, inspection, reporting requirements and the provision of advice and guidance.

Licensing – The legislation prescribes certain activities that can only be undertaken by a licensed establishment.

We license establishments across six sectors:

- Post Mortem, Public Display, Research and Anatomy (under the Human Tissue Act 2004)
- Human application – tissues and cells used in patient treatment - (under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which implement the EUTCD)
- Organ Donation and Transplantation (under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, which implement the EUODD)

The establishments we license must adhere to our standards, which align to our core principles.

Inspections or audits – We conduct site visits of licensed establishments in order to assess whether our standards are being maintained. We schedule inspections based on a number of factors, including the legislative requirements, and according to the risk of the activities being carried out. We continue to recognise the significant degree of trust that our licensed establishments have in us, as demonstrated by their openness and willingness to improve, which we believe is a key factor in the high level of compliance we see. As a result we only use significant regulatory action when it is appropriate and in the public interest.

We also undertake non-routine inspections, both announced and unannounced, when we have information which indicates that a site visit is required.

Reporting requirements – We require incidents and events which pose the highest risk to public confidence and patient safety to be reported to us by licensed establishments. This allows us to take action if required and ensure that any lessons learnt can be shared.

Advice and guidance – We place a great emphasis on providing advice and guidance to both the public and professionals, and recognise the value in supporting establishments to comply, rather than dealing solely with non-compliance. We publish a range of sector specific advice and guidance, as well as answering
individual enquiries from establishments and members of the public. We also provide advice and guidance as part of our inspection reports.

**Living donation assessment** – The HTA maintains a system to ensure that donations of organs or tissue for transplantation from living people are given without coercion or reward. The system relies on donor and recipient interviews, undertaken by a group of independent and accredited assessors. They are predominantly volunteers who we train, accredit and support in order to fulfil our statutory functions, and to whom we offer our thanks and appreciation. Complex cases are reviewed by panels, made up of HTA Authority Members.

**Communication and engagement** – We recognise communication as a key component of effective regulatory delivery. We utilise a range of channels to communicate with professionals, the public and key stakeholders to ensure that there is confidence in HTA regulation and in the services being regulated. We involve these groups to ensure we make decisions that take into account, as far as possible, the operational realities faced by professionals and the concerns of the public. Our formal groups, which report to the Authority include:

- Stakeholder and fees group
- Histopathology working group
- Transplantation advisory group

In 2017, we also established our public panel and licensed establishment engagement panel, which provide fora for wider participation and further opportunities for those interested or affected to be involved in, and inform, our work.

**Working with other organisations** – Many of the establishments within our remit are also regulated or accredited by other bodies. We continue to see collaboration as a key tool for achieving benefits for professionals and the public that produces joined up results, reduces our costs or reduces regulatory burdens. The HTA has bilateral agreements with the following:

- The Care Quality Commission;
- The Health Research Authority;
- The Human Fertilisation and Embryology Authority;
- The Medicines and Healthcare products Regulatory Agency; and
- The United Kingdom Accreditation Service.

Our Delivery objectives are:

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

In the period covered by this Strategy, we will:

- Ensure that new applications meet appropriate standards before issuing a licence;
- Use our knowledge of risk in each sector to drive the delivery of the right mix of regulatory tools to support compliance;
- Undertake a risk based program of site visits which provide assurance that standards are being maintained;
- Continue to publish exception based reports of inspections in the interests of transparency and to share learning;
- Take a proportionate and risk based approach to non-compliance, and ensure that where there are shortfalls against standards, these are rectified within agreed timescales;
- Ensure decisions on living organ donation cases meet agreed service standards in a way that provides the necessary protections;
- Engage with, and involve, public and professional stakeholders in our work using a wide variety of channels;
- Use the results of our public evaluation to create awareness of what drives public confidence, what the public are most interested in, and why.
- Seek out opportunities to build new collaborations for the benefit of stakeholders.
Development

To make the right investment to continuously improve delivery.

To ensure that the HTA’s regulatory approach remains relevant, we actively prepare for the future. We do this through our development activities. As outlined in the Strategic Review section, in this three year period our development goals will focus on building our resilience, agility and overall sustainability as an organisation in addition to maintaining our programme of continuous improvement activity.

Innovation - We see innovation across all the sectors we regulate and actively horizon scan to keep abreast of developments to inform our work, often in collaboration with other organisations. The pace of change requires a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells.

Where emerging issues can be accommodated within the current regulatory framework, we will work to achieve this with agility, proportionality and appropriate assessment of risk. Where they cannot, we will advise relevant Government, professional and public stakeholders, and actively consider the use of soft law tools where this is appropriate.

In the Human Application sector, we will continue to work closely with the Medicines and Healthcare products Regulatory Agency and other regulatory bodies on the Regulatory Advice Service for Regenerative Medicine (RASRM), which we see as a key foundation for the future regulation of novel tissue and cell therapy based products. We will further strengthen our regulation through implementation of the recommendations from our recent review of risk in the Human Application sector.

In living organ donation, we are seeing increasingly complex cases and wider use of paired and pooled donations, placing pressure on staff resource. The sustainability of the Independent Assessor framework remains a significant strategic issue, and we have undertaken a project to review options for putting this on a more sustainable footing, with a view to implementation during 2018/19.

Improving compliance - Although in general we see a high level of compliance in our establishments, we have recently seen a number of issues emerge which have had an impact on compliance in the Post Mortem sector. We will use the data and information we hold, and our close links with key stakeholders, to implement a programme of work aimed at addressing these issues.

Better use of data and information – We already use data and information to inform our risk based approach to regulation. We recognise that we can improve the quality and make better use of the data and information we hold, in order to ensure we prioritise and target our resources effectively across the organisation.

Organisational change - In addition to seeking improvements in our regulatory processes, this strategic period will see us invest significant resources in developing our people, business technology and estates planning. Balancing resources for development and improvement against our core delivery activities will mean a
greater emphasis on being clear about our priorities, and promotion of a cohesive, organisation-wide approach to addressing key business concerns.

Further details on how we will shape our future approach are described in the deployment section of this Strategy.

**Influencing others** - We will ensure we reflect our experience of regulating our diverse sectors in submissions and dialogue on the future of regulation, particularly in the context of the Government’s Industrial Strategy and EU Exit. We will be available to offer advice and guidance to colleagues across government and beyond as and when it is needed.

Our development objectives are:

- Use our data and information to provide a sharper focus for our regulatory work, allowing us to target our resources effectively;
- Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;
- Provide an agile response to innovation and change in the sectors we regulate;
- Develop a blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

In the period covered by this Strategy, we will:

- Implement the recommendations from our evaluation of risk across the human application sector and amend our approach as necessary;
- Implement the recommendations from the Independent Assessor Sustainability project;
- Continue to work with establishments to ensure as smooth a transition as possible in implementing the EU Coding and Import Directives and any changes resulting from the UK’s Exit from the EU;
- Continue to develop our approach to engaging with licensed establishments as a key tool in ensuring compliance;
- Develop tools to improve how we prioritise and plan our regulatory activities and manage our resources, including more effective use of information and data;
- Continue to upgrade and develop our core business systems, website, and online portal to better meet our business needs and the needs of our stakeholders;
- Continue to use our unique position to advise Government in matters relating to our remit.
- Plan, develop and implement an organisational transformation programme.
Deployment

To make the most effective use of people and resources in pursuit of our goals.

Deployment underpins both our Delivery and Development activity; it is the choices we make about how we best manage our people and resources.

People – Our staff are our key asset and are fundamental to successful delivery of our objectives. Our staff survey gives us great reassurance that the HTA is a good place to work, but offers insight into areas we can improve. More fundamentally, in order to achieve our vision to be a more resilient and sustainable organisation by 2021, our People Strategy will require a significant review that will also influence our Estates and Business Technology plans.

We will consider options for widening the pool for recruitment outside London and the South East, as well as ways we can remodel our induction and training to allow staff to become competent more quickly and be less dependent on location.

As a small, expert regulator, it is imperative that we retain the specialist skills of our staff for longer, which is challenging with current pay restraints. We will continue to promote work/life balance and flexible working, with a renewed focus on effective line management, training and development to make the best use of our expert resources.

Estates – Our People Strategy, as outlined above will largely drive our approach to estates. We continue to control our accommodation costs as far as possible by sharing office space; however, our current lease expires in 2021 meaning that we need to evaluate future options.

We are mindful of the Government’s commitment to make public sector bodies less London-centric, and view the 2018 – 2021 period as an ideal timeframe for the HTA to develop its own future accommodation plans. Expanding our workforce outside London and the South East over this period gives us the opportunity to develop as an organisation that works remotely by design, whilst ensuring that our culture and connectivity are maintained. As well as allowing us to increase the geographic pool from which we recruit, this may also produce rental savings that could be reinvested to address emerging business needs.

Business technology – Our business technology has never been so crucial to the success of the organisation and underpins much of what we set out to achieve. Our new strategic vision will require development of IT architecture, which is not dependent on location in preparation for a future office move. We will support our staff with the technology they need to work effectively and efficiently, in the office and remotely. We also recognise the opportunities for technology, digital and data to improve the services we offer, reduce burden and target our resources most effectively.

We take our commitment to information and cyber security very seriously, and will strive to meet our obligations under data protection legislation, the National Data
Guardian’s data security standards and relevant UK Government cyber security frameworks.

**Finance** – The HTA is funded through licence fees and Grant-in-Aid from the Department of Health and Social Care. For a number of years we have worked hard to keep costs down by finding efficiencies, sharing office space and sharing Director and Head posts with the Human Fertilisation and Embryology Authority (HFEA). Our recent review of the arrangements with HFEA highlighted further opportunities to boost the resilience of both organisations by developing a stronger strategic alliance.

We are aware of the budget constraints faced by many of our licensed establishments and remain committed to living within our means. We will also more actively consider alternative income streams where these align with core business activity [DN: maybe too strong?]. As part of our sustainability programme, we aim to signal our budget intentions over the next three years, with a view to providing certainty on fee levels for establishments.

Our Deployment objectives are:

- Manage and develop our people in line with the People Strategy
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- Provide a suitable working environment and effective business technology, with due regard for data protection and cyber security
- Plan and prioritise our resources to carefully balance activity across the organisation

In the period covered by this strategy, we will:

- Act on the feedback provided by our staff surveys to address key issues of concern;
- Remodel our training and induction programme;
- Consider the introduction of a new senior RM role for technical development of staff across the organisation;
- Develop more formal arrangements for greater use of home working to support our recruitment strategy;
- Give greater priority to data management and risk, ensuring that we comply with our requirements under relevant Data Protection legislation;
- Give further consideration to alternative and additional income streams;
- Implement the recommendations of the shared services review with HFEA to improve the resilience of both organisations;
- Improve our video conferencing, online meeting and collaboration capabilities;
- Produce an options appraisal for different models of working as an organisation, which puts our staff at the heart of what we do.
Accountability

The Authority is made up of a Chair and eleven Members:
- Nine are appointed by the Secretary of State for Health;
- One is appointed by the Welsh Minister of Social Services and Public Health; and
- One is appointed by the Minister of Health in Northern Ireland.

The Authority is made up of both lay and professional Members and currently includes an organ donor and a transplant recipient. The professional Members of our board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial, academic and public sector experience.

The Authority’s primary role is to ensure that the HTA’s statutory responsibilities are met and discharged effectively. It achieves this by setting the HTA’s strategic direction and providing both support and challenge to an Executive, which is responsible for the delivery of these responsibilities on a day-to-day basis. While the Executive implements this Strategy by way of business plans, there are a number of mechanisms in places by which the Authority steers, scrutinises and reviews performance.

The Authority holds five board meetings per year, one of which is in public. These meetings provide the opportunity to assess a range of management information and more detailed reports on progress against elements of the Strategy. They also allow the Authority to hold the Executive to account for the HTA’s performance.

Standing items reported to the Authority include:

Chief Executive’s report – to provide an overall assessment of the HTA’s performance and strategic risks.
Delivery report – to provide assurance on the delivery of regulatory activities.
Development report – to provide assurance on the delivery of development activities.
Deployment report – to provide an update on the deployment of resources.

The board meetings also provide the main means by which the Authority sets the direction on issues of strategic importance that emerge over the course of the year.

The Authority is supported in its work by two standing committees:
Audit and Risk Assurance Committee; and
Remuneration Committee.
The Executive also holds quarterly accountability meetings with the Department of Health and Social Care to review progress with delivery of key performance indicators and the management of strategic risks.
### Draft Key Performance Indicators / Deliverables 2018/19

<table>
<thead>
<tr>
<th>Delivery</th>
<th>Undertake a risk based inspection/audit program</th>
<th>At least <em><strong>xxx</strong></em> site visits to take place during the business year across all sectors</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
<td><em>subject to resource planning we anticipate undertaking in the region of 200 site visits</em></td>
</tr>
<tr>
<td>Delivery</td>
<td>Take appropriate action for all regulatory non-compliances</td>
<td>100% of CAPAs implemented to address major or critical shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented</td>
</tr>
<tr>
<td>Delivery</td>
<td>Make appropriately evidenced decisions to agreed quality standards</td>
<td>100% of non-panel cases turned around in line with the quality criteria set out in the SOP, and within 5 working days</td>
</tr>
<tr>
<td>Delivery</td>
<td>Make appropriately evidenced decisions within agreed timeframes</td>
<td>100% of panel cases turned around within ten working days</td>
</tr>
<tr>
<td>Delivery</td>
<td>Respond to enquiries in a timely way</td>
<td>At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries</td>
</tr>
<tr>
<td>Develop</td>
<td>Report on our impact on patient safety and public confidence</td>
<td>Report provided to the Authority annually (July) on a series of measures, which provide the Authority with assurance in relation to HTA activities aimed at ensuring human tissue is being used safely and public confidence is being maintained.</td>
</tr>
<tr>
<td>Develop</td>
<td>Project: Deliver a project to implement the recommendations from the review of risk in the HA sector</td>
<td>Project red-amber-green (RAG) status remains amber or green during the course of the project</td>
</tr>
<tr>
<td>Develop</td>
<td>Programme: Deliver a licensed establishment relationships programme</td>
<td>To deliver the programme as agreed by HTA Management Group</td>
</tr>
<tr>
<td>Deploy</td>
<td>Reduce attrition rates through improved selection and targeted retention measures to retain staff</td>
<td>Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%)</td>
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<tr>
<td>Deploy</td>
<td>Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff</td>
<td>Percentage of Regulation Managers with more than one year of service (high risk if less than 85%) *review target of 85%</td>
</tr>
<tr>
<td>Deploy</td>
<td>Lead and advise on best recruitment procedures to maintain organisational capacity and capability</td>
<td>Number of vacancies reported monthly (high risk if more than three vacancies)</td>
</tr>
<tr>
<td>Deploy</td>
<td>Manage all development options offered to staff and evaluate courses to ensure quality delivery and learning effectiveness</td>
<td>80% of staff attending training courses agree that the skills and knowledge gained will be useful for knowledge, performance, career development or general wellbeing</td>
</tr>
<tr>
<td>Deploy</td>
<td>Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees</td>
<td>Actual income versus budgeted income (reported monthly) Actual spend versus budgeted spend (reported monthly) Actual cash reserves versus required reserve of £1.8m (high risk if deficit is more than 10%) (reported monthly)</td>
</tr>
</tbody>
</table>
| Deploy | Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees | Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health and Social Care Grant-in-Aid and devolved governments income) (reported quarterly)  
Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly) |
Annex B – Summary of discussions from Authority Strategy Away Day

Summary

High level feedback on each of the recommendations is included below.

Recommendations 4 (Deliver HA Risk Recommendations), 9 (Business Technology and Data) and 10 (People Strategy) were all agreed as the highest priority by Authority members.

Recommendation 8 (Estates plan) is viewed as a medium/high priority; and 3 (Public Research and Engagement) and 7 (Signalling budget intentions) were a mix of high, medium and low.

A note was made that recommendations 8, 9 and 10 should be the highest priority but these will take the longest time.

Recommendations 5 (legislative change - HA) and 6 (legislative change – living organ donation) were mixed high and low priority. There were two suggestions to combine 5 and 6 into one recommendation.

Recommendation 1 (Industrial Strategy) was seen as medium to low priority; and 2 (EU Exit) was seen as lower priority.

Comments

Recommendation 1 – The HTA should dedicate some development resource to a clear articulation of our contribution to the Industrial Strategy for Life Sciences, and to the production of a supporting action plan

Priority – medium to low
  - Acknowledge and agree to be active shapers
  - Link to possible sources of income, priority dependent on funding available

Recommendation 2 - The HTA should dedicate some development resource to assessing the opportunities and challenges posed by the UK’s exit from the EU as the terms become clearer.

Priority – Lower for now
  - ‘Watching brief’ for now. Raise priority as developments occur
  - Higher priority with a smaller team that will increase if required

Recommendation 3 - The public research should be used to influence public engagement planning and subsequent activities for the 2018-2021 strategic period.

Priority – mixed priorities from Members. Two low, one medium and one high
  - Internal communications if operating model changes
  - Focus on policy makers and stakeholders
  - How does awareness (or lack thereof) relate to public confidence?
- Should we resource public engagement, given people don’t know of our existence?
- Confidence in regulation of novel areas?
- Appropriateness of activities
- Communications resource should refocus on underpinning our other strategic objectives
- Prioritise communications on decision makers (public affairs perspective) and on high risk/high interest issues
- Public confidence not (necessarily) built by public engagement. Don’t conflate the two

**Recommendation 4** - *Adopt the recommendations of the human application sector risk review subject to project board and SMT approval and develop a package of projects to deliver these recommendations.*

Priority – high
- Resource implications of advice and guidance (consider also for research sector)
- Potential culture change how minor shortfalls/CAPA are managed
- Consider how sector is named
- May release resource

**Recommendation 5** - *The HTA should highlight areas of legislative change required in order to ensure patient safety and public confidence in response to scientific and technical progress in the human application sector.*

Priority – a mix of high and low
- Be creative within current regulations
- Should R5 + R6 be combined into a strategic objective on review of statute and regulations?
- Is it just legislative change?

**Recommendation 6** - *The HTA should continue to look for legislative vehicles that could be used to alter the relevant Regulations for the assessment of paired and pooled cases.*

Priority – predominantly high with one low priority
- (Incorporate with R5). Ability to change regulations (paired/pooled) vs changing HT Act). Positive impact on IA resource and living donor co-ordinator resource
- IA sustainability project should be captured in the strategy as high priority
- Look at other means of regulating living donation to deal with increasing numbers, including IA review
- Agree with R6, also look for ways to handle significantly more living donors
- Can we work better with existing processes without legislative change?
- Finding ways to pay for IAs time to increase their availability
- If we can’t change the legislation, could we improve the panel approval process?
- Does it need a change in legislation or regulations? Go for changing regulations

**Recommendation 7** - *The HTA should reach a view about signalling its budget intentions over the period to March 2021 in advance of the publication of 2018/19 fees.*

**Priority** – a mix of high, medium and low
- Is there access to funds from the Life Sciences Strategy to maintain confidence in HA sector?
- Signal that we will try not to increase fees and to live within our means
- Financial pressure can be managed by smart regulation (e.g. reducing unnecessary inspections etc.). More efficiency or more money is a non-starter so prioritisation & risk based regulation
- Reduce low risk activities (e.g. research and following up shortfalls)
- Focus on this rather than total budget and word as a 'statement of intent' rather than a definite commitment
- Ensure prioritisation more 'ruthless' to manage within budget
- Flexible inspection schedules – more short notice

**Recommendation 8** - *A high-level plan for Estates, based on the presumption of working remotely by design, should be developed for inclusion in the Strategy document that is published in April 2018.*

Priority – medium to high priority
- R10 should drive R8
- Option appraisal of different methods of working
- Retain remote working as an option vs ‘by design’
- Future flexibility
- Note culture and connectivity impact

**Recommendation 9** - *A high-level plan for business technology and data will be produced for review by the Authority at its meeting on 8 February 2018. This high-level plan would be delivered through a number of key projects over the three-year period of the strategy, with the ambition of the organisation being ready to operate in a new bespoke way, from April 2021*

Priority – high
- Concerns on security
- How much can we do ourselves?

**Recommendation 10** – *An outline of the key changes that will be required to the People Strategy should be produced for consideration by the Authority at its meeting on 8 February 2018*

Priority – high
- People are our only resource – so people strategy should drive estates strategy
- Create one or more hubs
- Remodel induction to avoid need for 6 months induction in London

R8, 9, 10 – higher priority but longer terms
Shared Directorate Review

Purpose of paper

1. To provide an overview of the recent review of the Joint Resources Directorate of the HTA and the Human Fertilisation & Embryology Authority (HFEA)

Decision-making to date

2. The review was undertaken between June and September 2017, with recommendations made to the Chief Executives in October 2017. The report was presented to the HTA Audit and Risk Assurance Committee on 1 February 2018.

Action required

3. To note the recommendations and agree the approach to further joint working between both organisations.

Background

4. The appointment of a new joint Resources Director for the HTA and HFEA was considered an appropriate time to undertake the first review of the operation of the organisations' joint Resources Directorate, since its inception in 2014. The review also considered what, if any, further opportunities exist for both organisations to work more collaboratively.
5. The review was undertaken between June and September 2017, with recommendations made to the Chief Executives in October 2017. The Chief Executives of both organisations have indicated support for the recommendations and the direction of travel has been discussed and agreed with the Senior Management Teams of both organisations. The recommendations can be found at Annex A to this paper.

Summary of findings

6. In broad terms, the review concluded that the current operation and function of the Directorate provides the outputs and support required by both organisations in terms of management of Finances, Facilities and in relation to HTA business technology and risk management.

7. Although outputs are achieved it is clear that there is considerable weighting on specific roles and that without the considerable effort and additional hours worked by some post holders there is some risk that the quality and timeliness of key outputs would be compromised.

8. The report makes ten recommendations, the first six of which are inter-directorate focussed, in terms of improved communication, with some review of job descriptions and responsibilities to rebalance the weighting across roles.

9. The final four recommendations are focussed on areas where further collaborative work could benefit both organisations, in terms of providing resilience and support for other corporate functions and where joint development of technology and accommodation solutions could be beneficial.

10. Work has already begun to implement the recommendations. Where appropriate updates will be provided to both Authorities and their Audit and Risk Committees on any significant developments.
Recommendations

Recommendation 1.

The Director of Finance & Resources to produce a consolidated meeting schedule for the joint directorate, on a rolling twelve-monthly basis.

Recommendation 2.

The wider responsibilities of the Director of Finance & Resources role should be clarified with each Chief Executive and passed annually for information to each organisation’s SMT.

Recommendation 3.

The role of Head of Finance should be aligned in terms of responsibility, activity and requirements across both organisations, with the role split evenly across HFEA and HTA.

Recommendation 4.

Finance job description should be reviewed to align, where possible, the roles and responsibilities of similar job holders. Consideration must be given to moving some elements of the Head of Finance role to other post holders.

Recommendation 5.

The content of directorate owned policies in each organisation should be reviewed and aligned where possible, with review dates brought together at the earliest opportunity.

Recommendation 6.

Head of Finance to ensure critical business continuity resilience exists, with essential activity able to be undertaken across both finance teams.

Recommendation 7.

Finance systems and interfaces should be reviewed at the next renewal date, to consider alignment, but primarily to ensure VFM and suitability going forward.

Recommendation 8.

A new HR management systems should be jointly procured across both organisations, providing additional capability for HR reporting and alignment of payroll processing.
Recommendation 9.

Closer working across wider corporate services functions, to include business technology, human resources and estates/facilities. This should be focused initially on change project activity, to provide resilience and sharing of best practice. In the medium term there is scope to consider joint support around administration functions such as payroll, HR administration and IT helpdesk services.

Recommendation 10.

Opportunities for closer working should be considered over the forthcoming 3 year strategic period, focused on likely office relocation and development of an approach to more flexible working arrangements.