Eighty-seventh Meeting of the Human Tissue Authority

Date 7 February 2019
Time 10.00 – 12.15
Venue Viceroy Suite
Grosvenor Hotel, 101 Buckingham Palace Rd, London SW1W 0SJ

Agenda

1. Welcome and apologies
2. Declarations of interest Oral
3. Minutes of 8 November 2018 HTA (01/19)
4. Matters arising from 8 November 2018 Oral

Regular Reporting
5. Chair’s Report Oral
6. Chief Executive’s Report HTA (02/19)
7. Delivery Report – Quarter Three 2018/19 HTA (03/19)
9. Deployment Report – Quarter Three 2018/19 HTA (05/19)

Committee and Advisory Group Reporting

Policy Issues
11. Code of Practice for Deemed Consent in England HTA (06/19)
12. HTA Strategy 2019-2022 HTA (07/19)
13. Authority Standing Orders Update HTA (08/19)
14. Any other business
Minutes of the eighty-sixth meeting of the Human Tissue Authority

Date 8 November 2018
Venue Viceroy Suite, Grosvenor Hotel
101 Buckingham Palace Road
SW1W 0SJ

Present

Members
Nicola Blackwood (Chair)
Dr. Stuart Dollow
Amanda Gibbon
Prof. Andrew (Andy) Hall
William (Bill) Horne
Prof. Penney Lewis
Prof. Dame Sally Macintyre
Prof. Anthony Warrens
Bishop Graham Usher
Dr. Lorna Williamson, OBE

Apologies
Glenn Houston
Dr. Hossam Abdalla

In attendance
Allan Marriott-Smith (Chief Executive)
Nicolette (Nicky) Harrison (Director of Regulatory Delivery)
Dr. Hazel Lofty (Director of Regulatory Development)
Richard Sydee (Director of Resources)
Dr. Chitvan Amin (Item 13)

Observers
Jeremy Mean (Department of Health and Social Care)
Jacky Cooper (Department of Health and Social Care)
Clare Wend-Hansen (Regulation Manager; minute taking)
Item 1 | Welcome and apologies
---|---
1. Nicola Blackwood (the Chair) welcomed Members, attendees and observers to the eighty-sixth meeting of the Human Tissue Authority (HTA).
2. The Chair noted that Jeremy Mean and Jacky Cooper would observe the meeting from the Department of Health and Social Care (DHSC). The Chair noted that Clare Wend-Hansen would also observe the meeting and record the minutes.
3. The Chair advised that an update from Bill Horne on the Stakeholder and Fees Group meeting would be included after agenda Item 11. Dr Chitvan Amin would join the meeting to present Item 13 on the introduction of deemed consent in England (34/18).
4. Members were advised that Dr Mike Osborne (RCPath) would be joining them after the meeting to give a presentation on the pathology sector and the role of RCPath from the perspective of a practitioner in the Post Mortem (PM) sector.
5. Apologies for absence were received from Authority Members Glenn Houston and Dr. Hossam Abdalla.

Item 2 | Declarations of interest – Oral
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6. The Chair asked Members if they had any personal or pecuniary interests to declare in relation to items of the meeting’s agenda; none were declared.

Item 3 | Minutes of 19 July 2018 – HTA (29/18)
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7. Ahead of the meeting, Members were asked to provide comments on the minutes of the Authority meeting held on 19 July 2018. The Chair advised that comments had been provided by Dr Stuart Dollow. These had been incorporated into the draft minutes, which were circulated in advance of this meeting.
8. The minutes were accepted as an accurate record of the
meeting.

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<tr>
<th>Item 4</th>
<th>Matters arising from 19 July 2018 – Oral</th>
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<tr>
<td>9.</td>
<td>The Chair noted that all actions from the 19 July 2018 Authority meeting were resolved, ongoing in nature or would be addressed by the Senior Management Team (SMT) during the meeting.</td>
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<td>10.</td>
<td>Richard Sydee provided an update on the HTA email account arrangements for Members. Members now have access to HTA email accounts via the ‘Work’ app and remote desktop. Arrangements were also being put in place for Members to be able to use the remote workspace to securely access and edit documents.</td>
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<td>11.</td>
<td>Members asked if it would be possible to work on HTA related documents off line.</td>
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<td>12.</td>
<td>The Chair asked Members for any further matters arising.</td>
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<td>13.</td>
<td>No other matters arising were raised.</td>
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<tr>
<td>14.</td>
<td>Action 1: Richard Sydee to provide further information on remote workspaces and the possibility of working on HTA related documents offline at the Authority Meeting on 7 February 2019.</td>
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<td>Item 5</td>
<td>Chair’s Report – Oral</td>
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<td>14.</td>
<td>The Chair updated Members on her meetings with stakeholders since the July Authority meeting, including:</td>
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<td>- The Royal College of Physicians (RCP);</td>
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<td>- Medicines and Healthcare products Regulatory Agency (MHRA);</td>
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<td>- Anthony Nolan Trust;</td>
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<td>- the Academy of Medical Royal Colleges (AMRC);</td>
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<td>- Genetic Alliance;</td>
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<td>- the Royal College of Pathologists (RCPPath);</td>
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<td>- United Kingdom Accreditation Service (UKAS);</td>
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<td></td>
<td>- the Academy of Medical Sciences (AMS).</td>
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<td>15.</td>
<td>Based on these discussions, the Executive are following up on opportunities for further collaborative work between the HTA</td>
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and partner organisations.

16. The Chair thanked Members for attending the Strategy Away Day in September and for their contributions and insight.

17. The Chair thanked Members in advance for their attendance at the HTA conference. This will be the HTA’s first full day conference, with a range of speakers in the morning and the opportunity for attendees to participate in round table discussion and feedback in the afternoon.

18. The Chair informed Members that 2017/2018 appraisals are complete subject to Member sign-off.

19. The Chair updated Members on plans for Member appointments. Discussions are underway with DHSC regarding the opportunities for reappointment and recruitment of new Members. A draft person specification has been agreed with DHSC, including the additional skills that are needed in relation to digital/organisational transformation and finance. The Chair thanked Jacky Cooper from DHSC for her support on the appointment process.

20. The Chair commented on the increased Parliamentary and media interest during the last quarter where the HTA has been directly mentioned:

- The Real Bodies exhibition, about which the Chair wrote to the Minister to express the HTA’s concerns;

- Issues relating to police holdings in Manchester on which, although not in remit, the HTA has been asked to provide advice;

- The Government’s Technical Notice on the quality and safety of organs, tissues and cells in the event that the UK leaves the EU without an agreement in place (a ‘no deal’ scenario). The HTA also responded to the Scottish Government’s request for comment on draft legislation that is being put in place as part of wider contingency planning.

- The Organ Donation (Deemed Consent) Bill, which has now passed to the House of Lords; there were no amendments following the third reading in the House of Commons.
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<th>Item 6</th>
<th>Chief Executive's Report – HTA (30/18)</th>
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<td>21.</td>
<td>Allan Marriott-Smith presented this item and introduced the report.</td>
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<td>22.</td>
<td>Members were informed that all five of the strategic risks were stable. As previously noted, a tightening labour market continued to pose challenges with recruitment. As part of the HTA’s Strategy, the SMT are exploring options to allow the HTA to recruit from a wider geographic pool in order to maximise opportunities to recruit high-calibre staff and retain the specialist skills of our staff for longer; however, there is recognition that this is challenging with current financial constraints.</td>
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<td>23.</td>
<td>Members were advised that the HTA attended its most recent quarterly accountability meeting with its sponsors at the DHSC on 16 October 2018. Discussions included funding for the HTA’s transformation programme, as well as preparedness for EU Exit and progress of the Organ Donation (Deemed Consent) Bill.</td>
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<td>24.</td>
<td>The Authority was informed that the HTA remains in correspondence with an organ donor matching website to establish the extent of the services being offered and to ensure the providers are clear on the legal position in the UK.</td>
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<td>25.</td>
<td>Allan Marriott-Smith updated Members on stakeholders who had raised concerns in relation to the Real Bodies exhibition. Members question whether further consideration may be given to non-legislative regulatory options. Both DHSC and the Executive were in agreement that this would require further exploration on the risk of legal challenge.</td>
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<td>26.</td>
<td>Members asked for further clarification on the handling of recent issues with clinical waste collection and disposal. Members were provided with assurances that the HTA had been in close contact with DHSC colleagues on the potential for the issue to impact on public confidence, and related media interest. Jeremy Mean confirmed to Members that this was primarily an NHS contract and environmental regulation issue and was handled accordingly.</td>
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27. Allan Marriott-Smith provided an update on recent activity to recommence plans for a commercial service requiring removal of tissue from the deceased at funeral director premises. The HTA will continue to engage with the service provider on a proportionate regulatory approach.

28. The Authority noted the content of this report.

Item 7 Delivery Report – Quarter Two– HTA (31/18)

29. Nicky Harrison presented this item and introduced the report.

30. Members were advised that the KPI summary at the beginning of the Delivery Report shows that regulatory delivery has broadly stayed on track over quarter two. A full inspection schedule had been maintained through the summer holiday period, despite this coinciding with a peak in new staff joining the HTA and undergoing induction and a range of challenging regulatory matters arising, some of which were novel or high profile in nature.

31. There was one critical shortfall reported during quarter two. This was a cumulative shortfall from a routine inspection of an establishment in the Human Application (HA) sector related to inadequate governance arrangements. This had been highlighted at the previous inspection of the establishment, but sufficient progress had not been made to address the findings.

32. The HTA has responded well to a number of regulatory challenges, whilst noting this has continued, at times, to be at the expense of staff feeling under pressure.

33. Nicky Harrison noted that identifying the causes of staff workload pressures and improving the efficiency and effectiveness of our regulatory delivery is a continuing high priority. She was pleased to note that good progress is now being made on taking forward actions to implement recommendations resulting from a review of findings in the PM sector.

34. Nicky Harrison also noted that following the ‘Safety KPI’ work
we are increasingly starting to analyse and use data from a range of sources, including inspections, HTARIs and SAEARs, in our operational planning and management, in order to better understand the profile of risk and how best to target our resource at priority areas.

35. It was noted that our analysis of data from inspections and incident reporting continues to show an increased level of shortfalls in the PM and HA sectors, but that this is variable; some establishments perform well, whilst others present with more significant, wide-ranging and deep-seated issues.

36. Nicky Harrison provided her own reflections from recently observed inspections. She commented on the thoroughness in approach to inspection by Regulation Managers (RMs) and gave some initial thoughts for improvement, including:

- managing workload more effectively;
- targeting opportunities for shared learning and information sharing;
- targeting inspections and making use of information where establishments may be co-regulated or accredited.

37. Professor Anthony Warrens enquired as to whether providing more information on the website could ease workload, by reducing enquiry numbers. Nicky Harrison advised that the website content was currently being updated and that enquiries data could be used to ensure that key information was available and easy to find. It was also noted that ongoing collaboration with key stakeholder organisations, e.g. RCPath, provided wider opportunities to disseminate targeted information to a range of audiences.

38. Professor Anthony Warrens queried whether serious adverse events and reactions (SAEARs) reported in the ODT sector were within HTA’s remit, where they related to clinical decision making. The Authority were informed that the definition set out in the legislation was used to determine whether an incident was a SAEAR and that NHSBT collate reports of all incidents and onwardly report those that meet the legal definition. The HTA and NHSBT regularly discuss incidents to ensure that they are correctly reported.
39. Members questioned if workload could be better managed by taking enquiries electronically and not by telephone. Members were advised that the Executive would consider this, however, demographics of enquirers and the nature of enquiries received would play a part in whether this was feasible.

40. Members asked about the ongoing issue around the Greater Manchester police holdings and asked if there was further action that the HTA could take on a national level. Members were advised that having reported this matter to the HTA as an incident, the licensed establishment concerned was progressing with a full audit of all tissue holdings, including those held under police authority, and no other issues had been identified so far. It is also understood that there had been further consideration of the broader issues underlying this incident by a sub-committee of the National Policing Council and that further consideration would be given to this by the relevant main committee sometime in the New Year. Nicky Harrison noted that whilst the HTA has no statutory role in relation to tissue taken and held under police powers, it was able to offer advice on good practice. Nicky Harrison and the Interim Head of Regulation (for the Post Mortem sector) will be maintaining links with the relevant Home Office policy colleagues over this matter, in accordance with the three-way Memorandum of Understanding between the HTA, Home Office and National Policing Council (formerly the Association of Chief Police Officers).

41. The Authority noted the content of this report.

**Action 2: Nicolette Harrison to consider options in relation to responding to telephone enquiries, which may alleviate workload.**

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<th>Item 8</th>
<th>Development Report – Quarter Two – HTA (32/18)</th>
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<td>42.</td>
<td>Dr. Hazel Lofty presented this item and introduced the report.</td>
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<td>43.</td>
<td>The Authority was informed work to embed the EU Directives on Coding and Import was nearing completion, pending updates to the HTA Customer Relationship Management (CRM) system which should take place following completion of</td>
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the CRM upgrade work. Regulatory oversight of these Directives is now considered business as usual. This includes all regulatory activity associated with the amended UK Regulations, including the anticipated increase in shortfalls and licence variations as a result of the introduction of the new requirements.

44. The Authority was informed that progress on the licensed establishment engagement programme, in particular work on an online forum, is progressing. After feedback from user testing this is likely to take a different approach. Pending SMT approval, the preferred option is to implement a blogging function. Members sought assurance that the blog would not replicate the current enquiries system and requested further information on the intended audience and anticipated impact on staff time. Dr Hazel Lofty responded that guidelines would be put in place and content commissioned internally and externally, informed by feedback from licensed establishments. Comments would be pre-moderated by the Communications team.

45. The Authority was also informed that work is underway to consider potential options for training of Designated Individuals and Persons Designated.

46. Members were advised that progress was ongoing with the Independent Assessors (IA) sustainability project, with a move to a continuous system of accreditation. New guidance has been developed with the aim to provide a more consistent approach for IAs.

47. Members were informed that there is a continued focus on licensed establishment engagement through the HTA conference and targeted communications, alongside other strategic engagement in partnership with other organisations.

48. The Authority was advised that progress with work to support the PM sector is progressing. A summary of findings from the sector is being compiled into a shared learning document which is planned to be published during quarter three. Members were advised that HTA continues to work with the PM sector through close stakeholder engagement with professional bodies and attendance at external events.
49. Members were informed that work is ongoing to review the use of organ perfusion devices in the UK and that the HTA intends to revise its regulatory approach in this area.

50. The Authority was updated on work undertaken with DHSC to plan for the UK’s withdrawal from the EU. This predominantly impacts on the Human Application and Organ Donation and Transplantation sectors, and included communications activity around the publication of the Technical Notice referred to in Item 5 and our continuing work with stakeholders to support them in planning their activities as far as possible given the limited information at present.

51. Dr Hazel Lofty also confirmed the HTA commitment to maintaining effective working partnerships with European colleagues beyond March 2019.

52. Members raised questions around what is likely to happen after EU exit in the period from April 2019 to March 2020. Dr Hazel Lofty responded that the HTA had been working closely with DHSC to plan for a range of outcomes which will be dependent on negotiations. The HTA has been liaising with NHSBT to ensure the continued exchange of organs with other countries. In the HA sector, the HTA has been planning for all eventualities, including where the UK becomes a ‘third country’. It was noted that the HTA has held discussions with key stakeholders in the HA sector to provide information where possible, and ensure that concerns are escalated to DHSC for consideration in the wider planning.

53. The Authority noted the content of this paper.

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<th>Deployment Report – Quarter Two– HTA (33/18)</th>
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<td>54.</td>
<td>Richard Sydee presented this item and introduced the report.</td>
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<td>55.</td>
<td>Richard Sydee informed the Authority that there has been a significant increase in HR resource allocated to recruitment activities in the last quarter. All RM posts have been filled; the Head of Planning and Performance and a Regulation Officer post remain vacant.</td>
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<td>56.</td>
<td>Richard Sydee informed the Authority that a revised forecast at</td>
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the mid-year point indicates a minor overspend of £9k against expected income. The HTA remains confident that it will manage forecasted income through appropriate controls on discretionary spending.

57. Richard Sydee said that there was a total deficit against budgeted licence fee income of £10k. This was due to companies in the HA sector closing.

58. Allan Marriott-Smith informed Members that work has begun on producing an updated version of the People Strategy, which will be presented for approval at the next Authority meeting in February 2019.

59. Members were advised that there continues to be a strong interest in flexible working arrangements, with particular interest in home-based working. The HTA is committed to move to a model of working remotely ‘by design’.

60. Allan Marriott-Smith informed Members that recruitment to two proposed senior RM roles remained on hold. Further consideration on the nature and scope of the roles will take place in quarter three.

61. Members were informed that two training courses were provided for staff in quarter two: ‘taking effective notes and minutes’ and ‘taking control of your time’.

62. Members were informed of management steps taken to ensure staff take their entitled leave. A stress survey will be commissioned which will include interviews with staff and aim to explore any stress associated with home based working and isolation.

63. Allan Marriott-Smith informed Members that implementation and migration to HR people by end of quarter 3 will not be achieved due to IT resource capacity constraints.

64. Members were informed that new laptop rollout will be complete by the end of the calendar year, and that work continued on the CRM upgrade.

65. Richard Sydee informed Members that an IT retendering exercise had been completed resulting in the current provider
Members questioned whether issues with current service provision had been factored into the decision making and assurances were provided that steps had been taken to address these.

66. Richard Sydee informed Members that the HTA is making steady progress with the remaining issues relating to the General Data Protection Regulation. This item was explored in detail at the ARAC meeting where Members were informed of issues and risk management of this area. A revised deadline of March 2019 has been agreed for key areas of compliance. Members discussed their view of the relative risks in relation to data retention and disposal and expressed concern over IT resource. The Executive shared Members’ concerns and were actively looking to bolster resource in this area of the business to ensure there was not a single point of failure.

67. Members requested an update on appointment to the Board Secretary post. Allan Marriott-Smith responded that this role had been successfully filled, with the successful applicant starting in the New Year.

68. Members asked if it would be possible to introduce a surcharge for late payment of licence fees. Richard Sydee responded that as the majority of licence holders were also public bodies, this was unlikely to be a viable option for the HTA.

69. The Authority noted the content of this paper.

**Item 10 Audit and Risk Assurance Committee Update – Oral**

70. Amanda Gibbon, Chair of the HTA Audit and Risk Assurance Committee (ARAC), provided the Authority with an update on the HTA ARAC meeting on 23 October 2018.

71. Members were informed that Clare Wend-Hansen had taken on the role of staff champion.

72. Amanda Gibbon highlighted the positive findings from the internal audit on Stakeholder Engagement, and Members discussed the work already underway to further strengthen engagement activity including the review of website content. The ARAC also reviewed the work undertaken as part of the ‘Safety KPI’, and commended Amy Thomas on the valuable
analysis which would be utilised in forthcoming communications and to inform our regulatory approach.

73. Members were also informed that the ARAC had planned a more fundamental look at how risks were reported and considered by the Committee. Members highlighted the need to reduce the volume of material reviewed in order to focus on the key areas of risk for the HTA.

74. Amanda Gibbon thanked Diane Galbraith, Head of HR, for her work on staff induction, which was the subject of the ARAC ‘deep-dive’. Members took assurance from the progress made on the suite of documents for RM induction, and provided feedback on a number of points.

75. Members were also informed that the ARAC had approved the updated Reserves Policy.

76. As noted in earlier discussions, Amanda Gibbon reiterated concerns related to IT resourcing and informed Members that this will be examined during the next ARAC meeting, particularly in relation to preparedness for the transformation programme.

77. The Chair thanked Amanda Gibbon for her update.

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<th>Item 11</th>
<th>Transplantation Advisory Group Update – Oral</th>
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<td>78.</td>
<td>Professor Anthony Warrens provided the Authority with an update on the matters of interest arising from the Transplantation Advisory Group meeting on 4 October 2018.</td>
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79. Members were informed that the Group received a presentation from an organisation seeking to introduce a living and deceased uterine transplantation service in the UK. TAG members were assured from the presentation that both scientific and ethical issues had been given due consideration. Professor Warrens noted that the organisation had sought early engagement with the HTA and regulatory oversight of this procedure would proceed in line with the HTA’s usual processes.

80. Members discussed future potential issues relating to
transgender individuals who wish to carry a child or be a surrogate, which continue to be subject to wider ethical debate. Professor Warrens responded that the science was not yet sufficiently advanced for this to be an immediate issue, and that the Authority could be assured that there was time for the ethical debate to take place, as well as learning from other groups globally as techniques advance.

81. Professor Warrens reported that TAG had also reviewed activities for the IA sustainability project, which was on target.

82. The Chair thanked Professor Warrens for his update.

### Stakeholder and Fees Group meeting update – Oral

83. Bill Horne outlined the matters of interest arising from the Stakeholders and Fees Group (SFG) Meeting held on 22 October 2018.

84. Members were advised that two new stakeholders had attended the meeting and that all of the attendees had fully engaged in the discussions. The new stakeholders addressed a gap in representation of the HTA’s stakeholders.

85. Bill Horne informed the meeting that the SFG had received an update on: findings in the Post Mortem sector and the associated development work including plans for publication of a summary of shared learning; the progress of work on deemed consent; planning for EU exit; and proposed fee increases for 2019/20.

86. Bill Horne described an issue that was raised by a stakeholder relating to routine removal of samples from individuals that have died after suffering from dementia. After discussion around consent requirements, it was concluded that regulation was not a barrier and that there were other reasons which may preclude the research taking place.

87. Bill Horne informed Members of potential sensitivities associated with the cessation of paediatric post-mortem services at a licensed establishment which resulted in these cases being transferred to another post-mortem facility.

88. Members were updated on horizon scanning issues including cosmetic and aesthetic products, organ perfusion devices and
public display exhibitions.

89. The Chair thanked Bill Horne for his update.

**Item 13  Strategy to 2021 update - Oral**

90. Allan Marriott-Smith provided Members with an update on the progress and next steps regarding the strategy to 2021. Allan thanked the Members for their contribution to the strategy at the Strategy Away Day.

91. Members were informed that work had started to map out further detail on plans for implementation of the strategy, although the timing of release of funds has restricted progress.

92. Allan Marriott-Smith informed Members of various priority topics under discussion with SMT around working remotely by design (including the associated HR issues), IT infrastructure, information management and governance and directing resources to targeting risk.

93. Members were informed that SMT were looking at options for increasing IT resource, including whether this should be in-house or contracted out. Consideration was also being given to areas where funding could potentially be used to help plan the HTA’s approach, and to establish more formal programme management arrangements within the organisation.

94. Allan Marriott-Smith advised Members that an updated version of the People Strategy would be provided at the next Authority meeting, along with a more detailed programme plan and a new strategic risk which aims to articulate the risk of delivering the transformation programme alongside business as usual activity.

95. Members asked for assurance around financing any additional posts into the next financial year. Richard Sydee responded that ongoing affordability would be factored into any decision making.

96. Members asked if the spend would be resource or from capital funds. Richard Sydee responded that part of the programme planning would include a profile of spend that will identify costs that will be either expensed in year or capitalised as assets.
97. The Authority noted the report.

**Action 3: Updated HTA Strategy, Digital Data and Technology Strategy and updated People Strategy to be presented at the February Authority meeting.**

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<th>Item 14</th>
<th>Introduction of deemed consent in England – HTA (34/18)</th>
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<td>98.</td>
<td>Dr. Chitvan Amin presented this item which gave an overview of the HTA’s work to produce amended Codes of Practice to support the introduction of deemed consent in England. These changes are being introduced via a Private Members’ Bill – the Organ Donation (Deemed Consent) Bill.</td>
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<td>99.</td>
<td>The Bill seeks to amend the interpretation of ‘appropriate consent’ set out in the Human Tissue Act 2004 (HT Act) to mean that where a person has not made a decision regarding organ donation during their life, or appointed a representative for this purpose, then consent may be deemed.</td>
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<td>100.</td>
<td>The Authority was reminded that subject to Parliamentary approval of the Bill, a public campaign would begin in April 2019. The Bill, with amended Codes of Practice and further regulations will need to be ready for implementation from April 2020.</td>
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<td>101.</td>
<td>Dr Chitvan Amin further advised the Members that as the Bill, as drafted, is not prescriptive, the Code of Practice will contain high level practical advice and guidance for professionals carrying out activities within the scope of the HTA’s remit, to reflect the HTA’s current interpretation of the law and regulatory practice. The HTA proposes to amend Code of Practice A and F to include guidance on the circumstances in which the person concerned is deemed to have consented to organ and tissue donation.</td>
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<td>102.</td>
<td>In addition, minor amendments may be required to the other HTA Codes of practice to reflect the amendments to the HT Act, and to the Code of Practice on the Human Transplantation (Wales) Act 2013 to reflect the changes introduced by the Bill.</td>
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<td>103.</td>
<td>Members were advised that faith and cultural considerations had featured prominently in ongoing discussions with stakeholders. The HTA will work in close collaboration with</td>
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NHSBT, DHSC and faith leaders to discuss practical guidance on how the donation can proceed, whilst recognising the importance of faith and culture, through a range of channels including: events, our existing standing advisory groups, targeted newsletters and the HTA website.

104. The HTA propose that the project be added as a KPI to the HTA business plan, so project progress and key milestones can be discussed in monthly HTAMG meetings and monitored by the Authority. Members will have close involvement in the project and consideration will be given to how best to make use of Members’ skills, knowledge and experience.

105. Members asked whether the Bill would result in amendments to legislation in areas other than England. Dr Chitvan Amin responded the Bill relates only to England. Wales has existing legislation for deemed consent and Northern Ireland will retain the existing requirements for express consent of the individual or family.

106. Members asked about the difference between a Private Members’ Bill and a Government Bill. Jeremy Mean responded that the Government chose to support this Private Members’ Bill and therefore was closely involved in the policy development.

107. Members asked if the guidance would include a role for the family in the consent process. Dr Hazel Lofty responded that she would circulate the parliamentary debate to Members, and that the Minister had made clear the intention that there would always be a conversation with the family. This is an area the HTA will have to consider carefully.

108. Members asked for clarification around the evidence provided by families on the wishes of the donor. Dr Chitvan Amin responded that this was an area to explore with NHSBT based on their experience of introducing the system in Wales.

109. Members asked if there be any extra resources given for this work. Nicolette Harrison responded that requests for resource were under consideration by DHSC and that a further update would be provided at the February Authority meeting.

110. Members noted the contents of this paper.
### Item 15  Fees for 2019-2020 update – HTA (35/18)

111. Richard Sydee presented this item and introduced the paper.

112. The Authority was asked to agree the increase of all HTA licence fees in line with the August Consumer Price Index inflation rate of 2.7%.

113. Members were advised that, since they had last discussed this matter, the HTA has undertaken a further review of its fees model. In line with recommendations made by the Authority, the HTA has adapted the fees model to provide further flexibility in relation to overhead apportionment.

114. The following material issues have been considered as part of setting budget for 2019/2020 financial year:

- the number and profile of licence holders and have identified varying levels of growth/contraction across the sectors;
- the limits on budget flexibility resulting from all Regulation Manager posts being filled;
- the changing landscape of public sector pay which could impact on pay constraints; coupled with significant pay growth in the NHS this could lead to recruitment and retention challenges if the HTA cannot keep pace with market rates.
- The HTA continues to see material increases in the cost of IT licences and in the travel and accommodation cost of staff conducting inspections.

115. The HTA proposes to conduct a more in-depth review of licensed establishments and the level of regulatory activity associated with each sector. This work will start in early 2019. Bill Horne confirmed that, following discussion, the Stakeholder and Fees Group raised no objections to the proposed increase but highlighted their wish to be involved at an early stage in
the consultation process for any new fee structure. During that consultation they would wish to be briefed on the efficiencies that the HTA had made in order to reduce pressure on fees.

116. Members noted the contents of this paper.

<table>
<thead>
<tr>
<th>Item 16</th>
<th>White space for non-agenda items</th>
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<tbody>
<tr>
<td>117.</td>
<td>Members asked if they could be notified earlier of any changes to meeting times, which would be helpful in arranging travel to meetings.</td>
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<tr>
<td>118.</td>
<td>Members asked about training sessions and suggested that the purpose and scope of these sessions could be clarified and agreed with Members. A query was also raised regarding Member and SMT participation in the out of hours rota for urgent transplant cases. The Chair responded that these questions would be addressed through an agenda item at the next meeting.</td>
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</table>

**Action 5:** Members to be given advance notice when session times change  

**Action 6:** Members to receive an update on training sessions

<table>
<thead>
<tr>
<th>Item 17</th>
<th>Any other business</th>
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<tbody>
<tr>
<td>119.</td>
<td>No other business was raised.</td>
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The meeting closed at 13:05
Chief Executive’s Report

Purpose of paper

1. This paper provides an overall assessment of the strategic risks currently facing the HTA as set out in Annex A. The paper also reports on other issues of strategic interest emerging between the last Authority meeting on 8 November 2018 and the end of January 2019, which are not reported elsewhere.

Decision-making to date

2. This report was approved by SMT on 24 January for submission to the Authority.

Action required

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

Overview of strategic risks

4. All five strategic risks (found in Annex A) were assessed to be stable as of January 2018. In its January assessment, SMT noted the reduction in attrition, the progress that had been made in recruitment to key posts and the increasing capacity and capability of the organisation. Three posts were vacant at the end of January, all of which are being redesigned to meet future capability needs.

5. Since the last Authority meeting, SMT has added a new strategic risk (six) Failure to achieve the benefits of the organisational transformation programme. This risk is
included for information. The Audit and Risk Assurance Committee will be analysing this risk as part of its deep dive during its meeting on 12 February 2019.

Other issues

HTA transformation programme

6. Considerable Executive focus has been directed to preparing the organisation for the transformation programme that will commence in earnest in the next business year. SMT has had a number of discussions about establishing and building the capabilities that will be required to deliver the programme. Preparations have also involved discussion with others who have recent expertise in the delivery of digital transformation to discuss programme design and governance and lessons learnt.

7. In addition, SMT will engage external support before the end of the business year to assist in the preparing for the programme. Specifically, it is seeking more formal advice on programme design and governance to ensure these are suited both to our size and to fit within our current structure and alongside existing governance arrangements. We will also begin to map our current (‘As Is’) business processes, which will need to be in place before any process redesign can be undertaken. Finally we will undertake an organisation-wide training needs analysis with a particular focus on the needs associated with the programme.

8. To ensure staff engagement in the change, we have scheduled all staff meetings and quarterly awaydays for the rest of the calendar year. The focus of all staff meetings will be immediate business priorities, while the quarterly events will focus on change.

9. Although we have had an agreement in principle to release reserves to fund the programme, the formal business case was submitted in January, and is still under consideration by the Department. The funding committed to preparatory work will be met with the additional funding already in place in the current business year.

10. ARAC will be testing the current level of preparedness at its deep dive in February.

Accountability to the Department of Health and Social Care

11. The HTA met with DHSC on 8 January 2018 as part of its regular quarterly accountability meetings. The key focus of these meetings is now on preparations for the UK’s exit from the EU. Other agenda items included:

- Organ Donation (Deemed Consent) Bill
- Recruitment and reappointment of Authority Members
- Business planning for 2019/20
- Proposed development of a taphonomy facility
• Updates to the Framework Document and Protocol for Public and Parliamentary Accountability

12. We also outlined our progress against key performance indicators, our current assessment of strategic risk and the 2018-19 in year financial position. The Department took assurance from the meeting and thanked HTA for their support in preparing for EU Exit.

13. Minutes of the October accountability meeting have been circulated with the Authority papers for information.

Authority appointments

14. A case has been submitted to the Department to re-appoint Members who have completed their first term and wish to continue for a second. At the time of writing we were awaiting an outcome on this matter and on the recruitment of two further Authority Members.

15. Following the resignation of Nicola Blackwood as HTA Chair in January 2019, Bill Horne was appointed by the Minister as Interim Chair. At the time of writing, there was not yet a Departmental decision on the timeline for making a permanent appointment.

All staff away day

16. An all-staff away day took place on Monday 17 December with the purpose of seeking and sharing views on how we will deliver the HTA strategy over the next two years. We reflected on the achievements over the year, took a look forward to the rest of the business year and the changes that are anticipated in the next business year. This was followed by interactive sessions which sought to draw out views and concerns about the proposed changes.

Staff survey actions

17. As part of the ongoing response to the results of the last staff survey, we will be undertaking a stress survey and audit prior to the end of the business year. This will involve an external provider, Capita, conducting a confidential survey that will be sent to all staff and ten structured interviews with a variety of staff at all levels and across teams.

18. The results of the survey and audit will then be analysed to make recommendations on how we can better manage stress across the organisation, as well as reviewing our policies and procedures. We will then receive a report with recommendations which will inform our next steps.
Remuneration Committee Meeting

19. The Remuneration Committee met in December and agreed the arrangements for senior staff pay awards for 2018. The Committee agreed to make a consolidated pay increase of 1.5% for eligible senior managers. This is the same as the consolidated award made to all other staff. The Committee also agreed to make a non-consolidated award to one senior manager in line with the recommendation set out in the DHSC senior pay guidance.

GDPR compliance

20. At the last ARAC meeting, the Executive undertook to look in detail at our progress towards full GDPR compliance in advance of the internal audit on this topic due to take place in early 2019.

21. SMT has spent considerable management time on scrutinising the current position and the gaps to be filled. An update was provided to ARAC in December which concluded that full compliance would be achieved by the end of March 2019, subject to the procurement of a new personnel records management system.

Annual conference

22. As Members will be aware, the HTA’s annual conference took place in November. This year the conference was a full day event, and separate from the public Authority meeting. The increased time allowed for presentations from a range of speakers and an opportunity for delegates to participate in sector specific, round-table discussions facilitated by HTA Members and staff.

23. Feedback from the event has been very positive, with more detail provided in the Delivery Report (HTA 03/19), which will be used in shaping plans for future events.

Complaints

24. The HTA did not receive any complaints in quarter three.
Overview: Risks reflect the strategy for 2019 - 2021. Our highest risks are the failure to manage expectations of regulation, which reflects the fast-pace of change within the sectors we regulate and the low likelihood of legislative change in the foreseeable future, and failure to utilise our capabilities effectively which is currently affected by recent staff changes.

Other notable risks: Uncertainty posed by EU Exit, which is largely dependent on outcomes of the ongoing negotiations and resource dedicated to 'no-deal' planning which impacts on other work. Dedicated resource required to produce a Code of Practice for opt-out consent in England.

Recruitment for Regulation Managers has been successful with only one post vacant. All appointees have now taken up post. A number of more recently recruited Regulation Managers are now signed off to support and lead. This will increasingly have a mitigating impact on risks 1 and 4. Recruitment to the Head of Planning and Performance (previously Head of Operations) post has been successful and the appointee has started in post.

Further funding has been secured which will enable us to expedite key pieces of work, however this does create challenges which will affect risks 1 and 4.

### Risk Management

#### Risk Assessment Matrix

<table>
<thead>
<tr>
<th>Risk</th>
<th>Nov 2018</th>
<th>Dec 2018</th>
<th>Jan 2019</th>
<th>Comments</th>
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<tbody>
<tr>
<td>1. Failure to regulate appropriately</td>
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<tr>
<td>(Risk to Delivery a-d)</td>
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<td>2. Failure to manage an incident</td>
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<td>(Delivery, Development and Deployment)</td>
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<td>3. Failure to manage expectations of regulation</td>
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<td>(Risk to Delivery e and Development c)</td>
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<td>4. Failure to utilise our capabilities effectively</td>
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<tr>
<td>(Delivery a) (Development a-d) (Deployment a, c and d)</td>
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<td>5. Insufficient, or ineffective management of, financial resources</td>
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<td>(Deployment b)</td>
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<tr>
<td>6. Failure to achieve the benefits of the organisational transformation programme</td>
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<tr>
<td>(Development objectives a-d)</td>
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#### Risk Management Plan

- **Risk to Delivery: Failure to regulate appropriately**
  - 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 Regulator Managers have increased the organisational capacity and strengthened our regulatory capability.
  - Recent recruitment has resulted in all but one Regulator Manager posts being filled, that vacancy having only arisen with effect from 1st January 2019.
  - Recruitment for other vacant posts is ongoing.
  - Despite achieving levels of candidate drop out at interview stage, we have been successful in our recent recruit selection tasks.
  - Our new Transport Officer will take up post shortly before the departure of the present Transport Officer (due to retirement).
  - The development of a revised induction programme for NMs is progressing well but a review of Standard Operating Procedures is required in order to achieve consistency with consistent training in up to date practice.
  - We are aware that there has been an issue with the speed at which new NMs are being inducted which is related to the pressure on existing staff who not only maintain SARS but are involved in other projects.
  - We are actively working to address this and have plans in place to manage an incident. These plans are complete and were tested during our audit.

- **Risk to Delivery: Failure to manage an incident**
  - The CIP was utilised to manage a building power outage during March 2018 and a regulatory issue in April 2018. Lessons learned were discussed at STAC, but the incidents were managed well.
  - We are aware that if there is a "no-deal" EU Exit, we could affect our ability to respond or regulate effectively. We feel the plans in place are adequate.

- **Risk to Delivery: Failure to manage expectations of regulation**
  - We continue to communicate our work and advice where appropriate.
  - There is ongoing dialogue with fellow and stakeholders about emerging issues as they arise to offer help in the media when necessary.
  - Communicating on an issue which is not within remit but which may adversely impact on public confidence is challenging. The number of perimeter issues shows no sign of decreasing. These issues and the planning for EU continue to occupy regulatory resources.
  - We are aware that we have staff operating in the frontline who may be challenged about issues beyond our control, which would impact on the delivery of our regulatory work.

- **Risk to Delivery: Failure to utilise our capabilities effectively**
  - We continue to be in a position to use the skills of our staff more fully.
  - Recruitment to RM posts has been successful, but without significant pressure.
  - Other roles have been harder to fill as a result of salary not TUC differentials with other organisations.
  - Workload and pressure continues to be monitored closely by the management team and the actions agreed as a result of the staff survey are now being implemented.
  - We achieved our planned position relating to GDPPR by 25 May 2018 implementation date and have an initial deliverable position. We have a plan, that would allow for improved compliance by the end of March 2019 but delivering this may require trade offs with first line regulatory activity.
  - We recognise that securing further funding pressure to maintain the remaining time. Delays could impact at risk where we do not have sufficient staff resource to deliver any additional pieces of work that extra funding has given. We note that there is further work to be done on our induction processes which requires more people resource then is easily available.

- **Risk to Delivery: Insufficient, or ineffective management of, financial resources**
  - Although we have a small decline in licence revenue it does not present a material challenge to achieving financial balance this year.
  - Our April invoice run has been conducted and we will continue to monitor debtor levels and for any further changes to licence numbers.
  - Funding secured to cover our increasing capital costs. This will impact on our ability to spend the cash received and we are therefore mindful that there is a risk of not spending the funds due to the level of effort/resource required to scope where it is needed.
  - WE will continue to engage in stakeholder discussions to understand the impact of future delivery targets.

- **Risk to Delivery: Failure to achieve the benefits of the organisational transformation programme**
  - This is a new risk for which we have begun to look at the outcomes and deliverables.
  - The risk has been scored as high impact and low likelihood due to the proximity of the programme.
  - The impact of 'high' recognises that aspects of the programme in particular IT related projects could have significant impact on the business should things go wrong.

#### Strategic Objectives

- **Delivery – to deliver the right mix of activity to main public and professional confidence**
  1. To deliver a right touch program of training, inspection and incident reporting, aligning our resources where there is most risk to public confidence and patient safety;
  2. To ensure we have the right mix of activity to achieve our strategic objectives;
  3. To provide high-quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;
  4. To be consistent and transparent in our decision making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing fairly with those who do not comply with our standards;
  5. To inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them, and influence them in matters that are important to us;
  6. To maintain our strategic relationships with other regulators operating in the health sector.

- **Development – to make the right investment in development to continuously improve delivery**
  1. To use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
  2. To make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;
  3. To provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements;
  4. To develop and blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

- **Deployment – to make the most effective use of our people and resources in pursuit of our goals**
  1. To manage and develop our people in line with the HTA’s People Strategy;
  2. To ensure the continued financial viability of the HTA whilst charging fair and transparent licence fees and providing value for money;
  3. To provide a suitable working environment and effective business technology, with due regard for data protection and information security;
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<thead>
<tr>
<th>REP</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tr>
<td>f</td>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate (Risk to Delivery objectives and SMT Development objectives)</td>
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<td>Regulatory model: X</td>
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<td>I</td>
<td>Preventative</td>
<td>Authority developed and approved the HTA Strategy</td>
<td>HTA Strategy published in April</td>
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<td></td>
<td>Risk Owner: Allan Marriott-Smith</td>
<td>Causes</td>
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<td>Reports to Authority of key decisions in Delivery Report</td>
<td>Satisfaction report made in November 2018</td>
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<td>• Failure to identify regulatory non-compliance</td>
<td>Regulatory decision making framework: X</td>
<td>Preventative</td>
<td>Outputs from annual strategy review translate into revised annual strategy</td>
<td>Annual strategy planning every day completed in September 2018</td>
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<td>• Regulation is not transparent, accountable, proportionate, consistent and targeted</td>
<td>Annual scheduled review of Strategy: X</td>
<td>Preventative</td>
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<td>• Regulation is not sufficiently agile to respond to changes in sectors</td>
<td>Approved HTA Business Plan 2018/19: X</td>
<td>Preventative</td>
<td>Sign off of the business plan by the Chair on behalf of the Authority and by sponsor department</td>
<td>HTA Business Plan to be published in April and approved by the Department of Health</td>
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<td>• Inadequate adherence to agreed policies and procedures in particular in relation to decision making</td>
<td>Quality management systems: X</td>
<td>Preventative</td>
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<td>• Poor quality or out of date policies and procedures</td>
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<td>• Failure to identify new and emerging issues within HTA remit</td>
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<td>• Failure to properly account for better regulation</td>
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<td>• Insufficient funding in regulated sectors</td>
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<td>• Risk-based approach to implementing import and Coding regulations ahead of 21 March 2018 deadline</td>
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<td>• Failure to deal with regulatory consequences of EU exit</td>
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<td>• Loss of public confidence</td>
<td>Management information and assessment presented to the Authority quarterly as part of the Deployment report</td>
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<td>• Compliance to patient safety</td>
<td>Quarterly report made in November 2018 Authority meeting</td>
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<td>• Loss of respect from regulated sectors potentially leading to challenge to decision and non-compliance</td>
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<td>• Reputational damage</td>
<td>Staffing levels and roles reported quarterly to the Authority</td>
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<td>Quality management systems</td>
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<td>• HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model</td>
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<td>• Inadequate adherence to the HTA People Strategy</td>
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<td>Training and development of professional competence</td>
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<td>• Specialist expertise identified at recruitment to ensure we maintain a broad range of knowledge across all sectors and in developing areas</td>
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<td>• Internal audit of quality management system adequacy and adherence</td>
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<td>• EU Exit</td>
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<td>• Use of existing regulatory models to manage the outcomes of ‘no-deal’</td>
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**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:**

<table>
<thead>
<tr>
<th>REF</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
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<tr>
<td>2</td>
<td>Insufficient capacity and/or capability (for instance, staff availability, multiple incidents or ineffective knowledge management)</td>
<td>5 3</td>
<td>Future, should event occur</td>
<td>3 2</td>
<td>Filled identified business-critical roles</td>
<td>1 2 3</td>
<td>Preventative</td>
<td>Monthly reports to HTAMG</td>
<td>Last report December 2018</td>
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<td></td>
<td>Failure to recognise the potential risk caused by an incident (for instance poor decision making, lack of understanding of sector, poor horizon scanning)</td>
<td></td>
<td>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td></td>
<td>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td></td>
<td>Preventative</td>
<td>Policies etc. reviewed annually, training specification and notes after incident reviews</td>
<td>Reviewed by ARAC October 2018</td>
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<td></td>
<td>Failure to work effectively with partners/other organisations</td>
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<td>Media handling policy and guidance in place, including regular media training for key staff &amp; Members with relevant scenarios, to supplement media release and enquiries SOPs</td>
<td></td>
<td>Media handling policy and guidance in place, including regular media training for key staff &amp; Members with relevant scenarios, to supplement media release and enquiries SOPs</td>
<td></td>
<td>Preventative</td>
<td>Policy reviewed annually, training specifications</td>
<td>Media policy to be reviewed.</td>
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<td></td>
<td>Breach of data security</td>
<td></td>
<td>Accessible lines to take and key messages for likely scenarios</td>
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<td>Accessible lines to take and key messages for likely scenarios</td>
<td></td>
<td>Preventative</td>
<td>Documented, incidents reported to Chair and in Delivery Report</td>
<td>Delivery report to Authority meeting November 2018</td>
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<tr>
<td></td>
<td>IT failure or attack incident affecting access to HTA office</td>
<td></td>
<td>Availability of legal advice</td>
<td></td>
<td>Availability of legal advice</td>
<td></td>
<td>Preventative</td>
<td>Lawyers specified in Critical Incident Response Plan, SMT updates</td>
<td>In place</td>
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<td></td>
<td>Consequences of ‘no-deal’ EU Exit affecting supply routes, staff availability or multiple incidents</td>
<td></td>
<td>Fit for purpose Police Referrals Policy</td>
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<td>Fit for purpose Police Referrals Policy</td>
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<td>Preventative</td>
<td>Annual review of policy (minimum), usage recorded in SMT minutes</td>
<td>Policy reviewed by Authority July 2018</td>
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<td>Onward delegation scheme and decision making framework agreed by the Authority</td>
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<td>Onward delegation scheme and decision making framework agreed by the Authority</td>
<td></td>
<td>Preventative</td>
<td>Standing Orders and Authority minutes</td>
<td>SO reviewed and agreed in 4 May 2017 (next review May 2019)</td>
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<td></td>
<td>Regulatory decision making framework</td>
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<td>Regulatory decision making framework</td>
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<td>Preventative</td>
<td>Reports to Authority of key decisions in Delivery Report</td>
<td>Satisfactory reports made in November 2018</td>
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<td></td>
<td>IT security controls and information risk management</td>
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<td>IT security controls and information risk management</td>
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<td>Preventative</td>
<td>SRO annual review and reports Internal audit reports</td>
<td>Cyber security review - agenda item at ARAC June 2018</td>
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<td></td>
<td>Critical incident response plan regularly reviewed and tested</td>
<td></td>
<td>Critical incident response plan regularly reviewed and tested</td>
<td></td>
<td>Preventative</td>
<td>Critical Incident Response Plan and notes of test, exported to SMT</td>
<td>CIP was used to manager a power outage during March 2018 and a regulatory incident arising in April 2018</td>
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<td>Evaluate test exercise of incident and feedback to all staff.</td>
<td></td>
<td>Evaluate test exercise of incident and feedback to all staff.</td>
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<td>Preventative</td>
<td>Process has been utilised twice in 2018, lessons learned papers to be presented to ARAC June 2018</td>
<td>Paper on EU Exit plans to be reviewed by SMT in January, and considered by Authority at February meeting</td>
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<td>EU exit plans in place</td>
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<td>EU exit plans in place</td>
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<td>Preventative</td>
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<td>2</td>
<td>Failure to manage public and professional confidence of human tissue regulator in particular stemming from limitations in current legislation or misperception of HTA regulatory reach</td>
<td>Risk to delivery objectives and Development of Risk Owner Hazel Lofty</td>
<td>4 4</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>Preventive/Detector</td>
<td>Stakeholder Group meeting</td>
<td>Authority minutes (including Public Authority Meeting)</td>
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</table>

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

- Scope of relevant materials e.g. waste products
- Licensing requirements e.g. transplantation research
- Regulation relating to child bone marrow donors
- Issues raised by emergence of social media e.g. non-related donors
- Strengthening of civil sanctions for non-compliance

**Matters which stakeholders/prescribers may expect to be outside regulatory scope**

- Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure
- Police holdings
- Products of conception and fetal remains
- Data generated from human tissue donors
- Funeral directors
- Forensic research facilities
- Cryopreservation
- Body stores / Taphonomy
- Import controlled materials
- Clinical waste
- Other
- Inadequate stakeholder management

**Effect**

- Diminished public confidence in the adequacy of the legislation
- Reduced public confidence in regulation of matters relating to human tissue
- Regulatory damage

**Actions to improve mitigation**

- Active management of professional stakeholders through a variety of channels including advice about relevant materials in and out of scope
- Active management of issues raised by the media – including the development of the HTA position on issues
- Regular reporting to DHSC sponsorship and policy team on matters which risk public and professional confidence
- Action where we believe it will support public confidence (e.g. publication of pregnancy remains guidance)
- Clear view of use of a 15 duty to report issues directly to Ministers in England, Wales and Northern Ireland as new issues emerge
- Legal advice now gives a clearer view of our Schedule 2, s. 20 powers
- Codes of practice and standards – provide greater clarity on matters inside and outside of regulatory scope were published April 2017.
- Circulation of principles within Code A to wider stakeholders was undertaken Quarter 3 2017/18
- Partial implementation of triennial review recommendations March 2017
- Plan to develop and strengthen the relationship with DAs
- Public research - gaining a better understanding of public confidence and the factors which impact it - complete Q2 2017/18
- Proactive horizon scanning and development of policy in emerging/complex areas Project complete Q3 2017, now business as usual

**Programme objectives**

- Delivered programme or work to improve relationships with licensed establishments
- Licensed establishment engagement programme established to inform work new FUR for internal group to agree focus for next business year
Regular meetings with DHSC policy team to inform planning for EU Exit and plan in place, including for a ‘no-deal’ scenario

Meetings diarised and actions recorded. Internal EU Exit lead identified. Quarterly updates provided to Authority in Development report, and substantive paper at February 2019 meeting

On track, but uncertainty remains

Technical notices published by DHSC on preparation for no-deal August 2018

Operational readiness guidance published 31 December 2018
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<tr>
<td>4</td>
<td>Failure to utilise people, data and business technology capabilities effectively (Risk to Delivery objectives a-e, Development a-d)</td>
<td>People</td>
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<td>d d</td>
<td>Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle</td>
<td>1 2 3</td>
<td>Preventative/ Monitoring</td>
<td>QMS reminders as policies due for review. SMT review of all revised policies</td>
<td>Regular review cycle recommenced in late summer</td>
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| Effect | People | Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle | 1 2 3 | Preventative/ Monitoring | QMS reminders as policies due for review. SMT review of all revised policies | Regular review cycle recommenced in late summer |

| Effect | Data | Data relating to establishments securely stored with the Customer Relationship Management System (CRM) | 1 2 3 | Preventative/ Monitoring | Upgrades to CRM, closely managed changes to CRM development. Normal audit of personal data security | CRM upgrade roll out to be scheduled following completion of UAT |

| Effect | Business technology | Staff training in key business systems | 1 2 3 | Preventative/ Monitoring | Systems training forms part of the induction process for new starters | Ongoing records of all new starters trained in key business systems |

| Effect | IT systems protected and assurances received from 3rd party suppliers that protection is up to date | 1 2 3 | Preventative/ Monitoring | Quarterly assurance reports from suppliers. Monthly operational cyber risk assessments. Annual SIRO report | Annual SIRO report presented to ARAC June 2018 |

| Effect | People | Development of new People strategy and organisational structure in summer 2018 | 1 2 3 | Preventative | Currently identifying opportunities to collaborate with others in the ALB sector to tap into these opportunities | NHSBT Training - Effective Line Manager one of suite of training days taken up (Aug-17 onwards) |

| Effect | Data | GDPR project underway to ensure data is compliant with new regulations - GDPR deadline 25 May 2018 | 1 2 3 | Preventative | GDPR delivery project | GDPR - achieved defensible position by May 2018. Action plan exists for full compliance by March 2019 |

<p>| Effect | Business technology | Identify refresher training and targeted software specific training needs | 1 2 3 | Preventative | | |</p>
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| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licenced establishments changes, leading to reduced fee income  
• Management fail to set licence fees at a level that recover sufficient income to meet resource requirements  
• Failure to estimate resource required to meet our regulatory activity  
• Poor budget and/or cash-flow management  
• Unexpected increases in regulatory responsibilities  
• Unforeseeable price increases / reductions in GIA | 4 4 | Ongoing | Budget management framework to control and review spend and take early action | 2 3 | 1 X X | All | Budgetary control policy reviewed annually and agreed by SMT | Last review February 2017 |
|     |                  |                   |                      |          | Financial projections, cash flow forecasting and monitoring | X | Monitoring | Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH | Last quarterly report November 2018 |
|     |                  |                   |                      |          | Licence fee modelling | X | Preventative | Annual update to fees model | Update agreed by the Authority November 2018 |
|     |                  |                   |                      |          | Rigorous debt recovery procedure | X | Monitoring | Reserves policy reviewed annually and agreed by ARAC | Last agreed by ARAC October 2018 |
|     |                  |                   |                      |          | Reserves policy and levels reserves | X | Monitoring | Reserves policy reviewed annually and agreed by ARAC | Last agreed by ARAC October 2018 |
|     |                  |                   |                      |          | Delegation letters set out responsibilities | X X | Preventative | Delegation letters issued annually | Issued in April 2018 |
|     |                  |                   |                      |          | Prioritisation when work requirements change | X | Preventative | Agreed business plan, monthly HTAMG and SMT reports | Last HTAMG report December 2018 |
|     |                  |                   |                      |          | Fees model provides cost/income information for planning | X | Preventative | Annual review of fees model, reported to SMT and Authority | Update to be agreed by the Authority November 2017. |
|     |                  |                   |                      |          | Annual external audit | X | Detective | NAO report annually | Last report in June 2018 - clean opinion |
|     |                  |                   |                      |          | Monitoring of income and expenditure (RS) | X | Detective | Monthly finance reports to SMT and quarterly to Authority. Quarterly reports to DH | Last quarterly report November 2018 |
|     |                  |                   |                      |          | Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) | X X | Detective | Quarterly Finance Directors and Accountability meetings | Last FDs meeting Nov 2017 |

**ASSESSED POSITION:**

**RISK TO DEPLOYMENT OBJECTIVE:** b

**RISK OWNER:** Richard Sydee

**INHERENT RISK:**

**PRIORITY:**

**PROXIMITY:**

**EXISTING CONTROLS/MITIGATIONS:**

**RESIDUAL RISK:**

**PRIORITY:**

**ACTIONS TO IMPROVE MITIGATION:**

**LINE OF DEFENCE:**

**TYPE OF CONTROL:**

**ASSURANCE OVER CONTROL:**

**ASSURED POSITION:**

<table>
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<tr>
<th><strong>CAUSE</strong></th>
<th><strong>EFFECTS</strong></th>
<th><strong>TYPE OF CONTROL</strong></th>
<th><strong>ASSURANCE OVER CONTROL</strong></th>
<th><strong>ASSURED POSITION</strong></th>
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<tbody>
<tr>
<td>• Fee payers unable to pay licence fees</td>
<td>• Payments to suppliers and/or staff delayed</td>
<td>Detection</td>
<td>NAO report annually</td>
<td>Last report in June 2018 - clean opinion</td>
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<tr>
<td>• The number of licenced establishments changes, leading to reduced fee income</td>
<td>• Compensatory reductions in staff and other expenditure budgets</td>
<td>Detection</td>
<td>NAO report annually</td>
<td>Last report in June 2018 - clean opinion</td>
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<tr>
<td>• Management fail to set licence fees at a level that recover sufficient income to meet resource requirements</td>
<td>• Increased licence fees</td>
<td>Detection</td>
<td>NAO report annually</td>
<td>Last report in June 2018 - clean opinion</td>
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<tr>
<td>• Failure to estimate resource required to meet our regulatory activity</td>
<td>• Requests for further public funding</td>
<td>Detection</td>
<td>NAO report annually</td>
<td>Last report in June 2018 - clean opinion</td>
</tr>
<tr>
<td>• Poor budget and/or cash-flow management</td>
<td>• Draw on reserves</td>
<td>Detection</td>
<td>NAO report annually</td>
<td>Last report in June 2018 - clean opinion</td>
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**Leading to:**

- Inability to deliver operations and carry out statutory remit
- Reputational damage and non-payment of fees
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<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
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<tbody>
<tr>
<td>6</td>
<td>Failure to achieve the benefits of the organisational transformation programme (Development objectives a-d)</td>
<td>Risk owner: Allan Marriott-Smith</td>
<td>Causes</td>
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<td>Programme and project benefits poorly defined and understood</td>
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<td>Inadequate programme and project governance arrangements</td>
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<td>Inefficient programme, project and change management skills</td>
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<td>Inadequate leadership of change</td>
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<td>Inability to access the necessary skills required at a affordable cost</td>
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<td>Lack of staff buy-in to change</td>
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<td>Management and lead stretch of delivering transformation alongside business as usual and other development activity</td>
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<td>Inefficient agility in (re)deploying people to change projects</td>
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<td>Realisation of single points of failure for DDAT and People Strategy</td>
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<td>Agreement to a phased delivery approach to avoid all or nothing investment</td>
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<td>Wasted public money</td>
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<td>Failure to achieve the central strategic intent of the Authority</td>
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<td>Reputational damage</td>
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<td>Staff demobilisation</td>
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<td>Data remains under-utilised</td>
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<td>Poorly developed, incoherent to meet future needs (cost, functionality)</td>
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<td>Seek external advice on programme design and governance</td>
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<td>Embed Benefits Realisation Management methodology within programme</td>
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<td>Introduce a Programme Management Office</td>
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<td>Authority approval to proceed at key checkpoints</td>
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<td>Undertake a formal training needs analysis for the Programme and the HTA more widely</td>
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<td>Training plan to encompass project and change management and HTA approach</td>
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<td>Development of procurement plan to deliver the DDAT Strategy</td>
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<td>SRGs identified for Programme and individual projects</td>
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<td>Schedule a regular programme of staff engagement events</td>
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<td>Establish an external stakeholder communications and engagement plan</td>
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<tr>
<td></td>
<td>Recruitment of new Authority Member(s) with digital and organisational change experience</td>
<td></td>
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<tr>
<td></td>
<td>Programme to become a focus for appropriate internal audit</td>
<td></td>
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<tr>
<td></td>
<td>Appointment of external critical friend to counter potential optimism bias</td>
<td></td>
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</tbody>
</table>
## Authority Report
### Delivery – Quarter three 2018/19

<table>
<thead>
<tr>
<th>Date</th>
<th>7 February 2019</th>
<th>Paper Reference</th>
<th>HTA (03/19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>7</td>
<td>Author</td>
<td>Nicolette Harrison</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<td>Author Contact</td>
<td><a href="mailto:nicolette.harrison@hta.gov.uk">nicolette.harrison@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

### Strategic objectives (Delivery)

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

### Relevant key performance indicators (KPIs)

1. 200 site visits to take place during the business year across all sectors (year-to-date)
2. Report provided to the Authority annually (Q2) on the outcomes of our regulatory interventions and the impact on patient safety and public confidence
3. At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)
4. 100% of Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented (reported monthly) [See KPI narrative on page 9]
5. 100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly)
6. 100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days (average reported monthly)

### Related Strategic Risks

1. Failure to regulate appropriately (objectives a-d & f)
2. Failure to manage an incident (all objectives)
3. Failure to manage expectations of regulation (objective e)
4. Failure to utilise our capabilities effectively (objectives a-e)

(See paper 02a/19 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was approved by SMT on 24 January for submission to the Authority.

Action required

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

Directors’ summary

5. Quarter three of the 2018-19 business year has seen us operating at full staffing complement for the first time in a long while, with a number of new Regulation Manager recruits all making good progress through their induction to enable them to support and lead inspections. They have also made a strong contribution to our broader regulatory activities, thanks to the breadth and depth of professional experience and expertise they have brought with them.

6. We have therefore been able to maintain the steady inspection schedule that had been re-established in quarters one and two, providing a solid underpinning for our regulatory delivery across all sectors, allowing us to be well on-track to delivering our full inspection and audit schedule for this year whilst also freeing-up some Regulation Manager resource to work on post-mortem sector development activity.

7. We have continued to observe higher levels of shortfalls, and higher numbers of more serious shortfalls, than in previous years across most sectors, with the more serious shortfalls being handled through our Corrective and Preventative Action Plan process.

8. We made good progress in analysing data from various sources (shortfall, incidents and compliance updates) in the post-mortem sector and are using this to provide a sector update to help establishments learn from experience across the sector and share good practice. We hope to publish this in the final quarter of this year.
9. One critical shortfall was reported during the period, which is referred to below.

10. This period has also continued to see a number of urgent, novel or high profile regulatory issues, some of which have received media coverage. We are mindful of the impact that this has had on the availability of resources to deliver other work.

Critical shortfalls

11. There was one critical shortfall found on inspection in quarter three. This was a cumulative shortfall arising from concerns about storage arrangements and the impact of inadequate temperature monitoring and appropriate follow-up action following temperature excursions. The establishment commenced corrective and preventative follow-up activity immediately following the inspection, pending agreement of the formal Corrective and Preventative Action Plan with the Regulation Manager after the final report was issued early in quarter four.

Investigations

New investigations

12. There has been one new investigation (03/18) in quarter three following an allegation of storage and use of bodies for anatomical examination without appropriate and valid consent. We are at an early, information-gathering stage, awaiting responses to the allegations from the Designated Individual.

Update on investigation reported in previous Delivery reports (HTA 31/18)

Investigation 02/18

13. The two linked organisations that were subject to this investigation went into administration earlier this year and subsequently winding-up orders were issued. The main entity, which was registered in England and Wales, has now entered receivership, with the Official Receiver having been appointed. The other entity has entered receivership under Scottish law. The HTA worked originally with the administrators and now with the Official Receiver to endeavour to ensure that samples and records are maintained and stored safely and that clients are contacted as appropriate. We are continuing to work with the administrators and the Official Receivers to try and ensure that clients samples are accessible in the future.

Non-routine site visit inspections

14. There were no non-routine site visit inspections in quarter three.
15. There was one CAPA follow-up site visit to one establishment in quarter three, this was within the post mortem sector.

**Police referrals**

16. 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 07/18**

17. The case relates to two incidents concerning removal of samples without appropriate consent that were identified during a routine inspection. The incidents had been dealt with internally but had not been reported to the HTA.

18. SMT carefully considered the factors in favour for and against police referral. These were:

**Factors in favour of referral**

19. The following may be regarded as public interest factors in favour of referral to the police:

   - The information indicating that there has been an alleged offence is assessed to be reliable;
   - The alleged offence under human tissue legislation is likely to have been part of a pattern of recurring conduct.

**Factors against referral**

20. The following may be regarded as public interest factors against referral to the police:

   - 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 offences concerned acknowledged the breach of human tissue legislation to the Authority and the person concerned has not attempted to conceal the matter;
   - It appears that the alleged offences were not a deliberate act and that they occurred as a result of a genuine mistake or misunderstanding.

21. SMT concluded that the factors against referral outweighed those in favour. SMT took the decision not to refer the case to the police.
Legal notices

22. We did not issue any Directions in quarter three.

Regulatory decision meetings

23. One regulatory decision meeting (RDM) was held in quarter three, this was a CAPA follow up from a previous RDM. The outcome was to continue with the current CAPA plan and follow up with another RDM in January 2019.

Reconsiderations, representations and appeals

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

Enquiries

General enquiries

25. During quarter three, we recorded 588 general enquiries (including body donation), compared to 736 in the previous quarter. The enquiries included:

a. 225 from members of the public about body donation (98 were received via email or phone, and in the post, and 127 via the website). This compares to 276 in the previous quarter.

b. 363 about licensing or other areas of our regulatory work, compared with 460 in the previous quarter.

26. Of these enquiries, 358 were received via the website, compared to 334 last quarter. Other enquiries are usually received by phone.

27. The HTA sets itself a KPI of responding to 95 percent of general enquiries (excluding body donation enquiries) in ten working days. Of enquiries received during quarter three, 92 percent were closed in our case management system within ten working days, compared to 92 percent in the previous quarter. Over quarter three, 98 percent of enquiries were responded to within twenty working days, with the average time taken in quarter three standing at five days. The cases that fell outside ten working days generally tended to involve more complex regulatory matters requiring more time and further discussions with other bodies.

Freedom of Information Act (FOIA) requests

28. We had 8 FOIA requests in quarter three, compared to 11 in the previous quarter. We publish FOIA responses on our website.
Stakeholder engagement

Stakeholder and Fees Group Meeting

29. In October we hosted the tenth meeting of the HTA Stakeholder and Fees Group.

30. Items on the agenda were: HTA licence fees 2019/20; England deemed consent update; Post mortem sector development project and report; EU exit and the publication of the Government’s technical notices; Horizon scanning.

31. Access to the full papers and minutes from this meeting are available on the HTA website here – https://www.hta.gov.uk/about-us/committees/stakeholder-group.

British Transplant Society Winter Ethics Symposium

32. A number of HTA staff attended and participated in the British Transplant Society’s Winter Ethics Symposium meeting in November, with Dr Chitvan Amin opening the event.

33. This event was focused on ‘Directed Altruistic Donation’, with a very well-received presentation and discussion session on the legal basis for this type of organ donation in the UK and the HTA’s role.

34. Attendees from the HTA were Nicolette Harrison (Director of Regulatory Delivery), Dr Chitvan Amin (Transplant Manager), Adam Wells (Transplant Officer) and Jennifer Cole (Transplant Officer).

Consulting the public on our public guides to the Codes of Practice

35. In quarter two we began the process of reviewing the public guides to our Codes of Practice, and this has continued into quarter three, with two Codes still to receive feedback.

36. Once we have completed the final two reviews, this feedback will be shared at the quarter four Authority Meeting with a plan for any subsequent updates.

The HTA Annual Conference 2018

37. The HTA Annual Conference took place during quarter three, with 150 people attending this year’s conference at Church House, Westminster. The overarching theme of the conference was: Regulation in an era of innovation and political uncertainty.
38. Speakers and presenters for this year’s event were:

- Dr Nicole Mather, Director of Life Sciences and Healthcare at Deloitte
- Judge Mark Lucraft QC, Chief Coroner of England and Wales
- Professor Bobbie Farsides, Professor of Clinical Biomedical Ethics at Brighton and Sussex Medical School
- Dr Janet Messer, Director of Approvals Service at the Health Research Authority
- Phil Walton and Bethan Moss, Regional Managers at NHS Blood and Transplant Wales

39. It was a very successful and well received day, with very positive feedback from delegates on the day and subsequently via an online survey, including:

a. 96% said they would recommend the event to others
b. 98% said they would attend another HTA conference
c. 94% said they enjoyed the event (agree/strongly agree)
d. 94% said the event provided helpful information that applied to their work
e. 89% thought the venue was suitable
f. 98% said the event was the right length

[n = 56]

Engagement around the development of the revised Code of Practice for deemed consent

40. In quarter three we continued to undertake stakeholder engagement to inform the amendment of our Codes of Practice in preparation for the introduction of Deemed Consent in England. An overview of this is given in HTA (06/19).
Delivery KPI narrative

Performance against 2018/19 KPIs

41. KPI 3 (timely enquiry responses) continued to be red for October, November and December, with the 95% target narrowly missed, as described earlier in this report. Further training on logging and closing enquiries has been provided to staff.

42. As agreed with the Authority, KPI 4 (timely completion of major and critical CAPAs) is not allocated a RAG rating; however, the performance target (90%) was not met for October, November or December, with performance for December being the lowest (42%). Five out of 12 major and critical shortfalls, with a December date for CAPA closure, were completed in time. While two of the seven CAPAs were assessed and resolved quickly by HTA following late submission of evidence, five outstanding CAPAs related to one establishment, four of which have since been closed. The performance figures for October and November are consistent with recent performance (82 and 86%, respectively).

43. 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 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine inspection</td>
<td>41</td>
<td>37</td>
<td>40</td>
<td>29</td>
<td>150</td>
<td>136</td>
<td>164</td>
</tr>
<tr>
<td>LAAV - new application</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>4</td>
<td>11</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>LAAV – variation</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Satellite site inspection</td>
<td>16</td>
<td>8</td>
<td>14</td>
<td>17</td>
<td>66</td>
<td>46</td>
<td>47</td>
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<tr>
<td>CAPA follow up</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Non-routine inspection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total sites visited</strong></td>
<td><strong>61</strong></td>
<td><strong>52</strong></td>
<td><strong>58</strong></td>
<td><strong>50</strong></td>
<td><strong>236</strong></td>
<td><strong>203</strong></td>
<td><strong>234</strong></td>
</tr>
</tbody>
</table>
Table Two: Closed HTARIs in the post-mortem sector

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

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

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

<table>
<thead>
<tr>
<th>HTARI Classification</th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</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>12</td>
<td>9</td>
<td>12</td>
<td>16</td>
<td>48</td>
<td>33</td>
<td>28</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>
<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>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>4</td>
<td>4</td>
<td>7</td>
<td>3</td>
</tr>
<tr>
<td>Disposal or retention of an organ against the express wishes of the family</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>9</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>6</td>
<td>0</td>
<td>0</td>
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<td>Major equipment failure</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>4</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>HTARI Classification</td>
<td>Q3 2018/19</td>
<td>Q2 2018/19</td>
<td>Q1 2018/19</td>
<td>Q4 2017/18</td>
<td>2017/18 Total Year</td>
<td>2016/17 Total Year</td>
<td>2015/16 Total Year</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
<td>------------</td>
<td>-------------------</td>
<td>-------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Post-mortem examination of the wrong body</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Release of the wrong body</td>
<td>4</td>
<td>2</td>
<td>4</td>
<td>3</td>
<td>15</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>4</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Serious security breach</td>
<td>5</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>8</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Viewing of the wrong body</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>PM cross-sectional imaging of the body of a deceased person included an invasive procedure for which consent had not been given</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>10</td>
<td>12</td>
<td>11</td>
<td>6</td>
<td>28</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>42</td>
<td>35</td>
<td>38</td>
<td>43</td>
<td>149</td>
<td>89</td>
<td>97</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Number of reported HTARIs</th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reported HTARIs</td>
<td>35</td>
<td>47</td>
<td>59</td>
<td>71</td>
<td>230</td>
<td>160</td>
<td>174</td>
</tr>
</tbody>
</table>

Table Three: Closed SAEARs in the human application sector

48. 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.
49. The table below describes the number of SAEARs that were closed in each period. This does not include any incidents that were, on investigation, found not to fit the criteria of a SAEAR. Further detail on each case can be found in Annex B.

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

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Event linked to Distribution</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>6</td>
<td>3</td>
</tr>
<tr>
<td>Event linked to End use</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Event linked to Materials</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</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>0</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Event linked to Processing</td>
<td>4</td>
<td>2</td>
<td>7</td>
<td>7</td>
<td>21</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Event linked to Procurement</td>
<td>9</td>
<td>4</td>
<td>14</td>
<td>4</td>
<td>18</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Event linked to Storage</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>10</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Event linked to Testing</td>
<td>3</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>6</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Event linked to Transportation</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Other process</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>8</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Total – Events</td>
<td>20</td>
<td>9</td>
<td>30</td>
<td>13</td>
<td>67</td>
<td>52</td>
<td>51</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>10</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td>Total – Reactions</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>12</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td>Total – Events and Reactions</td>
<td>20</td>
<td>10</td>
<td>32</td>
<td>14</td>
<td>79</td>
<td>60</td>
<td>58</td>
</tr>
</tbody>
</table>

Table Three B: Reported SAEARs in the human application sector

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

<table>
<thead>
<tr>
<th></th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reported SAEs</td>
<td>65</td>
<td>63</td>
<td>84</td>
<td>56</td>
<td>157</td>
<td>83</td>
<td>46</td>
</tr>
<tr>
<td>Number of reported SARs</td>
<td>13</td>
<td>11</td>
<td>7</td>
<td>8</td>
<td>27</td>
<td>24</td>
<td>22</td>
</tr>
<tr>
<td>Total</td>
<td>78</td>
<td>74</td>
<td>91</td>
<td>64</td>
<td>184</td>
<td>107</td>
<td>68</td>
</tr>
</tbody>
</table>
Table Four: Closed SAEARs in the Organ Donation and Transplantation sector

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

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

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

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Events</td>
<td>6</td>
<td>3</td>
<td>2</td>
<td>7</td>
<td>29</td>
<td>28</td>
<td>30</td>
</tr>
<tr>
<td>Reaction in Donor</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>1</td>
<td>7</td>
<td>5</td>
<td>5</td>
<td>17</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>10</td>
<td>7</td>
<td>12</td>
<td>47</td>
<td>46</td>
<td>42</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reported ODT SAEs</td>
<td>13</td>
<td>2</td>
<td>6</td>
<td>3</td>
<td>22</td>
<td>38</td>
<td>22</td>
</tr>
<tr>
<td>Number of reported ODT SARs</td>
<td>10</td>
<td>2</td>
<td>9</td>
<td>3</td>
<td>15</td>
<td>26</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>23</td>
<td>4</td>
<td>15</td>
<td>6</td>
<td>37</td>
<td>64</td>
<td>36</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
<th>2015/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approvals</td>
<td>17</td>
<td>17</td>
<td>13</td>
<td>14</td>
<td>59</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>Q3 18/19</th>
<th>Q2 18/19</th>
<th>Q1 18/19</th>
<th>Q4 17/18</th>
<th>17/18 Total Year</th>
<th>16/17 Total Year</th>
<th>15/16 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directed kidney</td>
<td>222</td>
<td>226</td>
<td>211</td>
<td>208</td>
<td>855</td>
<td>874</td>
<td>886</td>
</tr>
<tr>
<td>Directed altruistic kidney</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>Non-directed altruistic kidney</td>
<td>27</td>
<td>19</td>
<td>5</td>
<td>3</td>
<td>98</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Paired or pooled kidney</td>
<td>66</td>
<td>42</td>
<td>20</td>
<td>45</td>
<td>201</td>
<td>91</td>
<td>88</td>
</tr>
<tr>
<td>Directed liver lobe</td>
<td>9</td>
<td>11</td>
<td>4</td>
<td>8</td>
<td>36</td>
<td>46</td>
<td>42</td>
</tr>
<tr>
<td>Non-directed altruistic liver lobe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Directed small bowel</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>12</td>
<td>5</td>
<td>-</td>
</tr>
<tr>
<td>** TOTALS **</td>
<td>327</td>
<td>303*</td>
<td>304</td>
<td>302</td>
<td>1214</td>
<td>1163</td>
<td>1172</td>
</tr>
<tr>
<td>Number of cases considered</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approvals by the LDAT Panel</td>
<td>233</td>
<td>240</td>
<td>220</td>
<td>218</td>
<td>897</td>
<td>930</td>
<td>935</td>
</tr>
<tr>
<td>Approvals by Authority panels</td>
<td>94</td>
<td>63</td>
<td>84</td>
<td>64</td>
<td>317</td>
<td>233</td>
<td>237</td>
</tr>
</tbody>
</table>

*includes one case considered using the ‘emergency out of hours’ process.
Communications

Social media

56. In quarter three, the HTA’s Twitter account had 2,098 followers, up from 2,021 in the previous quarter. Our engagement rate increased to 1.3% from last quarter, with a peak of 28.6%.

57. On average, HTA tweets were seen by 926 people per day, a decrease from 1200 people per day in quarter two.

Table Seven:

<table>
<thead>
<tr>
<th>Month</th>
<th>Impressions</th>
<th>Profile Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>October</td>
<td>28.2K</td>
<td>1447</td>
</tr>
<tr>
<td>November</td>
<td>37.2K</td>
<td>1730</td>
</tr>
<tr>
<td>December</td>
<td>19.1K</td>
<td>690</td>
</tr>
</tbody>
</table>

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

a. **Living Donation**
   Information on IA training session that took place in November

b. **Corporate**
   About Nicola Blackwood’s participation on the Healthtech Advisory Board

c. **Post Mortem**
   Thanking Mike Osbourn (RCPPath) for his training session at the last HWG meeting.

d. **Corporate**
   Live streaming speaker presentations at the HTA conference.

e. **Post Mortem**
   Information about how the HTA regulates the PM sector during National Pathology Week.

59. There are 848 Facebook ‘likes’ on the HTA page, up from 828 in quarter two. The HTA also had 606 followers for its LinkedIn company page, up from 592 in the last quarter.
Digital communications and publications

Table Nine: Website users

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

60. The highest viewed pages in Q3 are:

a. How to donate your body  
b. Medical school search tool  
c. HTA Codes of Practice  
d. HT Act information

Table 10: Page views

<table>
<thead>
<tr>
<th>Highest viewed pages</th>
<th>Q3 2018/19</th>
<th>Q2 2018/19</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>2017/18 Total Year¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donating your body info</td>
<td>23,457</td>
<td>25,802</td>
<td>27,737</td>
<td>22,866</td>
<td>71,208</td>
</tr>
<tr>
<td>Medical school search</td>
<td>12,925</td>
<td>14,129</td>
<td>13,523</td>
<td>17,089</td>
<td>55,506</td>
</tr>
<tr>
<td>Codes of Practice and Standards</td>
<td>8117</td>
<td>6,572</td>
<td>7,605</td>
<td>8,664</td>
<td>33,017</td>
</tr>
<tr>
<td>Body donation FAQs</td>
<td>5633</td>
<td>6,562</td>
<td>6,415</td>
<td>10,281</td>
<td>34,503</td>
</tr>
<tr>
<td>Guidance for professionals</td>
<td>4899</td>
<td>4,338</td>
<td>4,694</td>
<td>5,746</td>
<td>22,115</td>
</tr>
</tbody>
</table>

¹ Data first collected in 2016/17
Newsletters

61. During quarter three, the HTA sent out a professional newsletter in December and a Living Donation News bulletin in October. The HTA public newsletter was also sent out in December.

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

Table 11: Professional newsletter

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2018</td>
<td>4,327</td>
<td>34%</td>
</tr>
<tr>
<td>July 2018</td>
<td>4,380</td>
<td>34%</td>
</tr>
<tr>
<td>September 2018</td>
<td>4,469</td>
<td>28%</td>
</tr>
<tr>
<td>December 2018</td>
<td>5,795</td>
<td>31%</td>
</tr>
</tbody>
</table>

Table 12: Living Donation News bulletin

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 2017</td>
<td>272</td>
<td>26%</td>
</tr>
<tr>
<td>November 2017</td>
<td>272</td>
<td>35%</td>
</tr>
<tr>
<td>January 2018</td>
<td>268</td>
<td>44%</td>
</tr>
<tr>
<td>July 2018</td>
<td>266</td>
<td>36%</td>
</tr>
<tr>
<td>October 2018</td>
<td>265</td>
<td>37%</td>
</tr>
</tbody>
</table>

Table 13: Public newsletter

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>October 2017</td>
<td>1,086</td>
<td>29%</td>
</tr>
<tr>
<td>December 2017</td>
<td>1,249</td>
<td>38%</td>
</tr>
<tr>
<td>February 2018</td>
<td>1,249</td>
<td>40%</td>
</tr>
<tr>
<td>June 2018</td>
<td>1,371</td>
<td>49%</td>
</tr>
<tr>
<td>August 2018</td>
<td>1,471</td>
<td>45%</td>
</tr>
<tr>
<td>December 2018</td>
<td>1,606</td>
<td>41%</td>
</tr>
</tbody>
</table>

Media coverage

63. During quarter three, coverage which directly mentioned the HTA included:

a. Letter to The Guardian about body donation: *Our mother wants to donate her body and we don’t want her to* (Guardian)
A columnist from the Guardian had contacted the HTA for information on body donation and specifically, whether there is a legal obligation for families to arrange for medical schools to collect the body of their deceased family members. The columnist argues that although there is not a legal obligation to carry out these wishes, there is a moral obligation to do so.

b. ‘How could I find £3,000 to pay for my mum’s funeral?’ (BBC)
This article discusses various alternatives to a 'standard' funeral, including direct cremation, DIY funerals, eco-burials and others. The HTA is mentioned in relation to body donation, covering the increase in body donation enquiries we have experienced in recent years, but stating that not every body can be accepted.

c. Esmée Hanna: Patient dignity must be central to appropriate disposal of body parts (The BMJ)
Dignity in healthcare should be enacted at every step of a patient’s care, including when parts of people’s bodies have to be disposed of, says Esmée Hanna. From Code A (guiding principles and the fundamental principle of consent) the following is quoted; “the disposal of human tissue should be managed sensitively and the method of disposal should be appropriate to the nature of the material”.

d. HTA Chair Appointed to Heath Tech Committee - Health technology expert panel meets for the first time (Gov UK)
A mixture of IT experts, clinicians and academics make up the Healthtech Advisory Board, whose function will be to look at how the NHS can harness the potential of technology and create a culture of innovation to improve patient outcomes and reduce the workload on NHS staff. The board will meet every quarter and will report to Health Secretary Matt Hancock. Nicola Blackwood, then the HTA Chair, was one of the board members.
## Annex B – SAERs / HTARI details

### 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-36279-P8Z0</td>
<td>Procurement</td>
<td>Loss of autologous PBSC during collection due to a technical issue with the collection technique, resulting in additional mobilisation treatment for a second harvest.</td>
</tr>
<tr>
<td>CAS-44338-D7G7</td>
<td>Procurement</td>
<td>Labelling issue identified prior to issue of unit. Procedures put in place to emphasise cross reference checks of unique ID labels with donor ID; ensure all extra labels are reconciled</td>
</tr>
<tr>
<td>CAS-45068-Q8Q8</td>
<td>Procurement</td>
<td>Due to other medical issues, an unlicensed procurement was undertaken by another medical professional at no detriment to the tissues. Unlicensed procurement labels have been introduced to ensure the cells are released under concession.</td>
</tr>
<tr>
<td>CAS-43909-X2D3</td>
<td>Distribution</td>
<td>Human error led to tissue being delivered to an incorrect destination, resulting in the cancellation of a planned procedure.</td>
</tr>
<tr>
<td>CAS-42039-X8H6</td>
<td>Procurement</td>
<td>Communication error resulted in donor having an additional day of apheresis that was not required.</td>
</tr>
<tr>
<td>CAS-44814-F1Y2</td>
<td>Other (please specify)</td>
<td>An equipment fault caused a loss of tissue. Most was salvaged and SOPs, training and risk assessments have been put in place to cover the action to take if such an event occurs again.</td>
</tr>
<tr>
<td>CAS-44755-V1B7</td>
<td>Transportation</td>
<td>Human error resulted in two consignments of tissue being transported outside the required temperature range. Refresher training, labelling of transport boxes and kit instructions have been implemented and amended to mitigate any reoccurrence of this error.</td>
</tr>
<tr>
<td>CAS-44076-B8V3</td>
<td>Testing</td>
<td>Tissue on which the full panel of serology tests had not been undertaken was not stored in quarantine. Procedures and training have been put in place to ensure samples without complete serology results are stored in quarantine.</td>
</tr>
<tr>
<td>CAS-47112-V4C9</td>
<td>Testing</td>
<td>Procedure for informing donors of serology test results was not followed, resulting in donor being initially informed of a false positive first test result before being given the second and more accurate negative confirmatory test.</td>
</tr>
<tr>
<td>Case Number</td>
<td>Process Event Linked To</td>
<td>Description of Event</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-45078-Q1B6</td>
<td>Procurement</td>
<td>Human error led to incorrect procedure being used that resulted in loss of sample. Client informed and updated training material released to prevent risk of re-occurrence.</td>
</tr>
<tr>
<td>CAS-45060-B7J9</td>
<td>Procurement</td>
<td>Cold packs for procurement were placed in freezer but subsequent transportation temperatures were not in line with validation and tissue sample failed quality checks. Client has requested storage regardless and tissue will be marked for concessional release. Training materials were updated.</td>
</tr>
<tr>
<td>CAS-44921-X9N2</td>
<td>Procurement</td>
<td>Human error led to introduction of contamination during procurement. Refresher training has been undertaken for harvesting of this tissue.</td>
</tr>
<tr>
<td>CAS-44869-H7F7</td>
<td>Procurement</td>
<td>Contamination identified as having occurred at some point during procurement.</td>
</tr>
<tr>
<td>CAS-45329-K7Q8</td>
<td>Storage</td>
<td>Incorrect positioning of temperature probe led to lack of detection of temperature deviation for one tissue sample in a storage vessel. The probe has been repositioned and procedures put in place to ensure correct positioning and enable accurate continuous temperature monitoring and alarm triggers.</td>
</tr>
<tr>
<td>CAS-45493-N4H6</td>
<td>Testing</td>
<td>Sample not suitable for mandatory serology testing because of delays in reaching the testing laboratory. Testing subsequently undertaken and were all negative.</td>
</tr>
<tr>
<td>CAS-44339-L1W6</td>
<td>Procurement</td>
<td>Initial positive test result for microbial contamination was succeeded by a negative test result. The contamination was attributed to human / procedural error at the point of collection. Relevant staff have been retrained, as a precautionary measure, in hand cleansing and aseptic practises.</td>
</tr>
<tr>
<td>CAS-40980-L2P7</td>
<td>Processing</td>
<td>Sampling contamination of tissue during processing. Subsequent testing of sample was negative for the contaminant identified. Patient engrafted.</td>
</tr>
<tr>
<td>CAS-41310-Y7L9</td>
<td>Processing</td>
<td>Contamination of tissue was detected in post processing sample however subsequent retesting was negative. Contamination likely due to poor sampling techniques.</td>
</tr>
<tr>
<td>CAS-41628-Z8W1</td>
<td>Processing</td>
<td>Contamination detected in post processing sample of tissue. Recipient given antibiotics and successfully engrafted.</td>
</tr>
<tr>
<td>CAS-41225-N0Q0</td>
<td>Processing</td>
<td>Human error in manual calculation resulted in sample being considered too small and discarded.</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-44518-J9B6</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-46842-V8W3</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-42202-B2X4</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-46432-F8C1</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-46857-R1Y9</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-46275-F6X9</td>
<td>ODT SAE</td>
<td>Damage to 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-41421-F4T1</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Organ rejection in recipient</td>
</tr>
</tbody>
</table>
### Post Mortem HTA Reportable Incidents

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Classification</th>
<th>Brief summary of HTARl</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-46006-C3J1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-44629-D0Z3</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-37030-Y0W0</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Human error led to unauthorised removal of tissue</td>
</tr>
<tr>
<td>CAS-41530-B9S1</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Human error led to unauthorised removal of tissue</td>
</tr>
<tr>
<td>CAS-44249-P3M7</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Failure to locate and communicate with family, resulting in a complaint about actions taken</td>
</tr>
<tr>
<td>CAS-45433-S4P4</td>
<td>Accidental damage to a body</td>
<td>Human error led to unauthorised removal of tissue</td>
</tr>
<tr>
<td>CAS-45184-C5Y0</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 the loss of traceability of tissue</td>
</tr>
<tr>
<td>CAS-44014-B3L5</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Inappropriate storage arrangements</td>
</tr>
<tr>
<td>CAS-46487-J2G5</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 the loss of traceability of tissue</td>
</tr>
<tr>
<td>CAS-42782-L7Q9</td>
<td>Serious security breach</td>
<td>Unauthorised individual gained access to the mortuary</td>
</tr>
<tr>
<td>CAS-41236-G4S5</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-41074-Y5T1</td>
<td>Post-mortem examination of the wrong body</td>
<td>Human error led to PM on the wrong body</td>
</tr>
<tr>
<td>CAS-45723-D4B5</td>
<td>Serious security breach</td>
<td>Human error led to a security breach</td>
</tr>
<tr>
<td>Case Number</td>
<td>Incident Classification</td>
<td>Brief summary of HTARI</td>
</tr>
<tr>
<td>-----------------</td>
<td>------------------------------------------</td>
<td>----------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-43045-B0P2</td>
<td>Serious security breach</td>
<td>Incorrect viewing procedure led to a security breach.</td>
</tr>
<tr>
<td>CAS-46300-K6W9</td>
<td>Release of the wrong body</td>
<td>Human error led to the short term release of the wrong body.</td>
</tr>
<tr>
<td>CAS-44990-N1W7</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Alleged incident occurred while viewing of the deceased</td>
</tr>
<tr>
<td>CAS-45092-X0H3</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 the loss of traceability of tissue</td>
</tr>
<tr>
<td>CAS-38483-F4R8</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>A crematorium alerted the mortuary to the fact that blocks and slides were being buried and not cremated</td>
</tr>
<tr>
<td>CAS-47087-D0D1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-46920-H7H9</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>An administrative error led to a delay in repatriating tissue to a body</td>
</tr>
<tr>
<td>CAS-45622-T7F3</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Retention of tissue resulting in a complaint</td>
</tr>
<tr>
<td>CAS-47389-R9F7</td>
<td>Serious security breach</td>
<td>Unauthorised access to the mortuary</td>
</tr>
<tr>
<td>CAS-44284-H1V8</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-46463-N3W6</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Human error led to removal of tissue from a body without appropriate consent</td>
</tr>
<tr>
<td>CAS-46465-K6S7</td>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>Human error led to removal of tissue from a body without appropriate consent</td>
</tr>
<tr>
<td>CAS-46250-X0H5</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>Case Number</td>
<td>Incident Classification</td>
<td>Brief summary of HTARI</td>
</tr>
<tr>
<td>------------------</td>
<td>------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-43592-Z3W4</td>
<td>Viewing of the wrong body</td>
<td>Procedural error lead to the viewing of a wrong body</td>
</tr>
<tr>
<td>CAS-44993-Q0Z1</td>
<td>Release of the wrong body</td>
<td>Human error led to the release of the wrong body</td>
</tr>
<tr>
<td>CAS-45615-W2N1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-45450-T6P7</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-46555-W5V3</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-45080-Y6G6</td>
<td>Release of the wrong body</td>
<td>A procedural error led to the temporary release of the wrong body</td>
</tr>
<tr>
<td>CAS-41963-P1S7</td>
<td>Discovery of an organ or tissue following post-mortem</td>
<td>Procedural error led to a delay in the disposal of tissue</td>
</tr>
<tr>
<td></td>
<td>examination and release of body</td>
<td></td>
</tr>
<tr>
<td>CAS-45169-Q9Z4</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a body</td>
</tr>
<tr>
<td>CAS-47358-S6F9</td>
<td>Loss of an organ</td>
<td>Gap in procedures led to loss of an organ</td>
</tr>
<tr>
<td>CAS-47190-W0T6</td>
<td>Release of the wrong body</td>
<td>Human error led to the short-term release of the wrong body</td>
</tr>
<tr>
<td>CAS-45343-B5T7</td>
<td>Any incident not listed here that could result in</td>
<td>Human error led to unauthorised retention of tissue</td>
</tr>
<tr>
<td></td>
<td>adverse publicity that may lead to damage in public</td>
<td></td>
</tr>
<tr>
<td></td>
<td>confidence</td>
<td></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>
<tr>
<td>CAS-38843-P8P1</td>
<td>Any incident not listed here that could result in</td>
<td>Human error led to the loss of traceability of tissue</td>
</tr>
<tr>
<td></td>
<td>adverse publicity that may lead to damage in public</td>
<td></td>
</tr>
<tr>
<td></td>
<td>confidence</td>
<td></td>
</tr>
<tr>
<td>CAS-46515-P3Q5</td>
<td>Disposal or retention of a whole fetus or fetal tissue</td>
<td>Disposal of tissue contrary to the wishes of the family</td>
</tr>
<tr>
<td></td>
<td>(gestational age less than 24 weeks) against the express</td>
<td></td>
</tr>
<tr>
<td></td>
<td>wishes of the family</td>
<td></td>
</tr>
<tr>
<td>Case Number</td>
<td>Incident Classification</td>
<td>Brief summary of HTARI</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>CAS-45693-J5D6</td>
<td>Accidental damage to a body</td>
<td>Human error led to minor accidental damage to a deceased person</td>
</tr>
<tr>
<td>CAS-41843-P4Y5</td>
<td>Serious security breach</td>
<td>Procedural error led to unauthorised access to the mortuary</td>
</tr>
</tbody>
</table>
# Authority Report

## Development – Quarter Three 2018/19

<table>
<thead>
<tr>
<th>Date</th>
<th>7 February 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>8</td>
</tr>
<tr>
<td>Paper Reference</td>
<td>HTA (04/19)</td>
</tr>
<tr>
<td>Author</td>
<td>Hazel Lofty</td>
</tr>
<tr>
<td>Author Contact</td>
<td><a href="mailto:hazel.lofty@hta.gov.uk">hazel.lofty@hta.gov.uk</a></td>
</tr>
</tbody>
</table>

## Strategic Objectives (Development)
- Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
- 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, making it clear how to comply with new and existing regulatory requirements;
- Develop a blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

## Relevant KPIs (marked as red, amber, green, black or blue)
1. PROJECT: Assessment of Risk in the Human Application sector and update of processes to reflect this
2. PROJECT: Deliver a project to implement EU Directives on Coding and Import
3. PROGRAMME: Deliver a licensed establishment relationships programme as per plan specification
4. Develop our People and ICT Strategies as the first step in planning our organisational transformation programme
5. PROJECT: Develop a revised code of practice to provide practical guidance on the implementation of deemed consent for organ donation

## Related Strategic Risks (marked as red, amber or green)
1. Failure to regulate appropriately (objectives a-d)
2. Failure to manage an incident (Delivery, Development and Deployment objectives)
3. Failure to manage expectations of regulation (objective c)
4. Failure to utilise our capabilities effectively (objectives a-d)

(see paper 02a/19 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was approved by the Senior Management Team (SMT) at its meeting on 24 January 2019.

Action required

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

Director’s summary

5. Quarter three saw steady progress on a number of planned development activities, although prioritisation of resources to training new Regulation Managers, particularly in the Human Application sector, has meant that progress on less critical activities has been slower than initially anticipated. However, the increased numbers of Regulation Managers should allow for greater flexibility in dedicating resource to development work in quarter four and beyond.

6. An increase in activity in both the introduction of Deemed Consent in England, and preparations for the UK’s exit from the European Union, has also occupied development resource.

7. Engagement with licensed establishments remains a focus, and was a feature of the HTA conference which took place in quarter three. The feedback was overwhelmingly positive and we are well placed to consider how to build on this success for future events. Other work to support engagement continues, with the blog functionality on the website now in development.

Project updates

Core 2018/19 projects

8. The five projects below were considered core during 2018/19.
EU Coding and Import Directives implementation

9. As noted in the previous development report, the majority of the work required to implement these Directives has been completed. Regulatory oversight of the changes is considered business as usual.

10. The KPI for this project remains amber as residual system changes to CRM are still pending. These changes will provide a distinction between the different types of import licensing and authorisation in our licensing records system. The changes are scheduled to be implemented following completion of the CRM upgrade work.

Licensed establishment relationship programme

11. In quarter three, we updated the Project Overview Document (POD) which sets out the programme’s priorities and scope. In the revised POD, we have emphasised a more collaborative and open approach between the Communications Team, Policy and Regulation Managers on projects and pieces of work aiming to improve engagement with those working within the HTA’s regulatory remit. Looking ahead, internal membership of LEEP is open to all Regulation Managers. However, we will require a certain level of commitment and representation from each sector team.

12. Work is still ongoing to develop an online test on questions covering the HT Act. The draft questions have been collated and are awaiting approval from Heads and pending testing from the wider Regulation Team before eventual roll out on the HTA website.

13. Work continues to scope the available options for potential DI training packages, evaluating the resource required and impact this might have.

14. Members will recall that work on developing an online forum was paused, awaiting a decision from SMT on next steps and actions. Following the Christmas and New Year break, SMT reviewed a paper on the options, and took the decision to develop a blog function on the HTA website as an additional engagement channel. This reflects feedback from establishments during our research into establishing the online community, and will also address one of the recommendations of the Stakeholder Engagement Audit. Development work has already started, and we expect the blog to be live during quarter four.

Assessment of risk in the human application sector

15. Prioritisation of resource to training new Regulation Managers has meant that limited progress was made on this project in quarter three.
16. The Audit Risk and Assurance Committee has received updates on progress made in the oversight of Third Party Agreements, which was identified as a key risk area for this project.

17. Regulation Manager resource has been dedicated to this project for quarter four. It is anticipated that the majority of recommendations associated with oversight of third parties, and with preparation process dossiers, will be well in train by the end of the business year and will continue into the next business year.

Organisational Transformation Programme

18. Further detail on progress with the organisational transformation programme is provided in the Chief Executive’s report.

Introduction of Deemed Consent in England

19. Further work has been undertaken on the production of amended Codes of Practice as a result of the Organ Donation (Deemed Consent) Bill, currently in Parliament. We are also carrying out stakeholder engagement work to seek views on faith and cultural considerations. A more detailed overview is given in paper HTA (06/19)

Additional 2018/19 projects

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

EU Exit

21. In quarter three we have continued to work closely with the Department of Health and Social Care in planning and preparing for EU Exit. Towards the end of the quarter, an increased focus was placed on contingency planning for a ‘no deal’ scenario and operational preparedness. In response, we have reviewed and updated our plans and continue to liaise closely with DHSC colleagues and the wider health ALB family through regular meetings.

22. We have advised licensed establishments to refer to relevant publications on the Gov.uk website for information and to contact us with any technical enquiries about how to prepare. We have also signposted information released to frontline NHS staff by the Secretary of State for Health and Social Care.
Development of a Safety KPI

23. Since producing a comprehensive report for the last business year on the HTA’s regulatory and licensing outcomes, the focus for the 2018/19 business year has been on using our data and information to provide real-time analysis. Primarily, we have considered inspection outcomes and incident reporting.

24. Through this analysis we have identified trends in inspection findings and used this to provide targeted guidance in the post mortem sector. We are intending to broaden this approach to other sectors in quarter four.

25. We will also be feeding the established data analysis models into other project work including fees modelling and risk-based inspection approaches.

Sustainability of the Independent Assessors framework and continuous accreditation for Independent Assessors

26. The new process for reaccreditation of Independent Assessors (IA) will be rolled out from April 2019. Training webinars on this process have been scheduled for this month. These have been publicised in the Living Donation newsletter and will also be made available to view via the portal for IAs that are unable to attend.

27. A draft code of conduct for IAs was drafted in quarter three and will be released following legal review.

28. We have also developed a suite of mandatory and non-mandatory training packages for IAs. These will be released in the next business year.

PM Development Work

29. Work to support compliance in the PM sector is ongoing with different areas of focus that interlink. The main areas are:

   PM sector publication

30. The PM sector publication is a review of findings from inspections since April 2017 and HTARI incident reports. The aim of the publication is to feedback information to the sector but the data analysis has helped the HTA to identify areas that require improvement. Therefore, the publication also includes good practice and advice on how to meet the licensing standards to help increase compliance in the sector. The
publication is in the final stages of review and will be published by the end of March 2019.

Guidance for the standards

31. The guidance in support of the licensing standards is undergoing a full review to help increase understanding of requirements to meet the standards and help increase compliance. Where common shortfalls have been identified under the new standards, the current guidance is frequently limited. An example is Traceability standard T1(c), in relation to the use of three identifiers to identify bodies and tissue. The updated guidance now includes additional information for establishments. The updated guidance for T1(c) is already on the HTA website and has been communicated to the sector in the e-newsletter.

Targeted advice and guidance

32. In addition to updating the guidance in support of the standards, inspection reports are being reviewed to identify common themes and advice given to individual establishments, but would benefit establishments across the sector. The targeted advice and guidance will be issued via the e-newsletter, as and when this is required.

Ex-vivo Organ Perfusion

33. Earlier in the business year, a targeted review was carried out on the use of organ perfusion devices in the ODT sector. Through horizon scanning, we are aware that organ perfusion techniques are routinely applied throughout the UK, however there is inconsistency in practice between centres.

34. Our review has identified areas where the HTA needs to strengthen its regulatory oversight in this area, as well as opportunities for greater collaboration with other regulatory bodies. The review will make a number of recommendations that, if approved by SMT, will be taken forwards in the next business year.
Development KPI narrative

Performance against 2018/19 KPIs

35. Development KPI 1 (HA Risk), KPI 2 (EU Directives) and KPI 3 (Licensed establishment engagement) are marked as **amber** to reflect progress against milestones.

36. All other Development KPIs for quarter three are within target or tolerance and marked as **green**.
# Authority Report

**Deployment – Quarter Three 2018/19**

<table>
<thead>
<tr>
<th>Date</th>
<th>7 February 2019</th>
<th>Paper Reference</th>
<th>HTA (05/19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>9</td>
<td>Authors</td>
<td>Richard Sydee Allan Marriott Smith</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>
</table>

## Strategic objectives (Deployment)

- **a)** Manage and develop our people in line with the HTA’s People Strategy;
- **b)** Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money;
- **c)** Provide a suitable working environment and effective business technology, with due regard for data protection and information security;
- **d)** Plan and prioritise our resources to carefully balance activity across the organisation.
### Relevant KPIs (marked as red, amber, green, black or blue)

<table>
<thead>
<tr>
<th>KPI</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>Reduce attrition rates through improved selection and targeted retention measures to retain staff. Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly).</td>
</tr>
<tr>
<td>12.</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. Percentage of Regulation Managers with more than one year of service (high risk if less than 80%) (reported quarterly). Consideration of Senior Inspector role (Q1). Plan for remodelling of RM induction and training programme (Q1). Roll out of new programme (Q4).</td>
</tr>
<tr>
<td>13.</td>
<td>Lead and advise on best recruitment procedures to maintain organisational capacity and capability. Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly).</td>
</tr>
<tr>
<td>14.</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. 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>
<tr>
<td>15.</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. Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health Grant-in-Aid and devolved governments income) (reported quarterly); Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly).</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 02a/19 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was considered by the Senior Management Team (SMT) at its meeting on 24 January 2019.

Action required

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

Director’s summary

5. Overall, people related risks appear to be reducing. Key vacancies, which have been open for some time have now been filled and, while there will be further staff losses in quarter four, we are hopeful that these will be filled quickly. The attrition rate is currently at a historically low level of 12.8% and the capacity and capability of the RM pool is strengthening.

6. Part of the additional funding that was released during quarter three has been used to boost the spending on group training needs which had been identified but not delivered due to budget constraints. In addition we have been able to use some of the funds to undertake further work on strategically important initiatives; allowing us to manage stress more effectively, and to understand better our current capabilities in readiness for organisational transformation.

7. To the end of December 2018 net expenditure is £120k lower than originally budgeted, this is due to additional Ring Fenced Resource DEL funding provided to HTA at the end of November 2018. We anticipate that our full year outturn position will be a surplus of £80k.

People

People Strategy

8. The new version of the People Strategy covering the period 2019 to 2021 will be presented for comment at the February Authority meeting.
9. The Regulation Manager induction process project has now been completed and will be rolled out by Heads of Regulation as new starters join the HTA.

10. A facilitated session involving Regulation Managers who joined the HTA in 2017 and Heads of Regulation will take place early in the new year to allow Heads to have a better understanding of current induction experiences and where changes can be made to ensure a consistent and positive experience for new starters.

11. Staff attended Equality, Diversity and Inclusion and Transgender Awareness training with overall feedback being positive including a desire for further training and initiatives in this area.

12. A further eight group training courses have been booked and offered to staff across the organisation, these courses are Implementing Policy, Root Cause Analysis, Clean Room Training, Negotiating and Influencing, Writing Written Briefs, Pathology Training and Unconscious Bias and Interview Skills for line managers.

13. In addition to the group training courses we have been able to offer a number of training courses for individuals to support development needs identified as part of our performance development planning (PDP) process.

14. Following a period of significant recruitment, we are moving into a more stable period, with the majority of new starters having now joined us and attrition sitting well under the 18% KPI at 12.8%.

Finance

Financial position for Q3 2018/19

15. For the nine months of the 2018/19 financial year, we are reporting a surplus against budget of £192k.

16. The table below shows the summarised financial position as at 31 December 2018, which is made up of an over recovery in our income of £72k and an under spend in revenue expenditure of £120k.
Table One: Income and Expenditure summary – December 2018

For the Nine Months Ending 31 December 2018

<table>
<thead>
<tr>
<th>Year to Date</th>
<th>Actuals</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td>(4,648,094)</td>
<td>(4,575,774)</td>
<td>(72,320)</td>
<td>1.58%</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>3,500,185</td>
<td>3,620,011</td>
<td>(119,827)</td>
<td>-3.31%</td>
</tr>
<tr>
<td>Net (surplus)/deficit of income over expenditure</td>
<td>(1,147,909)</td>
<td>(955,763)</td>
<td>(192,147)</td>
<td>20.10%</td>
</tr>
</tbody>
</table>

INCOME

17. Income for the nine months ended December 2018 is above budget by £72k. Two-thirds of our Grant in aid cash allocation has been drawn down and we have now billed all of the six sectors. There is a small surplus against budgeted licence fee income of £0.4k.

18. Significant variances to budget are within the Research sector where we have exceeded budget by £14k, which represents new satellite licences issued; application fees £9k over budget. Against this is the shortfall in the Human Application sector £16k which relates to revocations and corrections and under recoveries in other sectors with the ODT sector under recovering by £7k.

19. The income from secondments are over budget due to an additional secondment of a staff member to DHSC. Income from rent is over budget due to a share of VAT being passed to our sub-tenants.

20. Table 2 below gives a full breakdown of income streams and their respective variances to budget.
Table Two: Income Summary – September 2018

Member Income Summary

For the Nine Months Ending 31 December 2018

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
<td>Variance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Grant In Aid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GIA</td>
<td>528,000</td>
<td>527,250</td>
<td>750</td>
<td>0.14%</td>
<td></td>
</tr>
<tr>
<td>Non-cash income</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.00%</td>
<td></td>
</tr>
<tr>
<td>Sub-Total</td>
<td>528,000</td>
<td>527,250</td>
<td>750</td>
<td>0.14%</td>
<td></td>
</tr>
<tr>
<td>Licence Fees</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Application Fees</td>
<td>41,820</td>
<td>32,500</td>
<td>9,320</td>
<td>28.68%</td>
<td></td>
</tr>
<tr>
<td>Anatomy</td>
<td>93,000</td>
<td>93,760</td>
<td>(760)</td>
<td>-0.81%</td>
<td></td>
</tr>
<tr>
<td>Post Mortem</td>
<td>1,153,985</td>
<td>1,155,760</td>
<td>(1,775)</td>
<td>-0.15%</td>
<td></td>
</tr>
<tr>
<td>Public Display</td>
<td>20,787</td>
<td>18,950</td>
<td>1,837</td>
<td>9.70%</td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>643,972</td>
<td>630,150</td>
<td>13,822</td>
<td>2.19%</td>
<td></td>
</tr>
<tr>
<td>Human application</td>
<td>1,401,859</td>
<td>1,417,870</td>
<td>(16,011)</td>
<td>-1.13%</td>
<td></td>
</tr>
<tr>
<td>ODT</td>
<td>290,270</td>
<td>297,170</td>
<td>(6,900)</td>
<td>-2.32%</td>
<td></td>
</tr>
<tr>
<td>Sub-Total</td>
<td>3,645,693</td>
<td>3,646,160</td>
<td>(467)</td>
<td>-0.01%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other income (Rent)</td>
<td>272,856</td>
<td>255,400</td>
<td>17,456</td>
<td>6.83%</td>
<td></td>
</tr>
<tr>
<td>Other income (Secondees)</td>
<td>70,464</td>
<td>28,293</td>
<td>42,171</td>
<td>149.05%</td>
<td></td>
</tr>
<tr>
<td>Devolved Assemblies</td>
<td>131,081</td>
<td>118,671</td>
<td>12,410</td>
<td>10.46%</td>
<td></td>
</tr>
<tr>
<td>Sub-Total</td>
<td>474,401</td>
<td>402,364</td>
<td>72,037</td>
<td>17.90%</td>
<td></td>
</tr>
<tr>
<td>Total Income</td>
<td>4,648,094</td>
<td>4,575,774</td>
<td>72,320</td>
<td>1.58%</td>
<td></td>
</tr>
</tbody>
</table>

EXPENDITURE

21. Table three below shows that our total revenue expenditure is under budget by £120k with £98k relating to staff salaries and wages and the balance of £22k to Non-staff costs.

22. The variance within staff costs (£98k) relates to vacancies that were carried for a period of time. However, as of December all posts have been recruited to with new starters commencing in January onwards.
Table Three: Summary Expenditure – December 2018

For the Nine Months Ending 31 December 2018

<table>
<thead>
<tr>
<th>EXPENDITURE SUMMARY</th>
<th>Year to Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
</tr>
<tr>
<td>Staff Costs</td>
<td>2,142,951</td>
</tr>
<tr>
<td>Non Staff Costs</td>
<td>1,357,234</td>
</tr>
<tr>
<td>Total Expenditure</td>
<td>3,500,185</td>
</tr>
</tbody>
</table>

23. Within our non-staff costs the following areas have a variance (over/underspend) of more than £5,000 and these are:

a. Travel and Subsistence costs (£5k) below budget with Members travel being £4k below budget. This is largely due to forward planning of travel thus reducing costs.

b. Within Training and Recruitment, we are underspending by £6k on training a reduction of £13k from quarter two. A push on the career investment scheme and corporate training has paid off. Offsetting this underspend is an overspend on recruitment costs £13k which reflects the recent successful recruitment rounds.

c. There are underspends within our Conference and Project costs (£16k) due lack of activity. In particular an underspend of £8k in Conference travel costs where work pressures have prevented staff from attending conferences. Business Planning and staff engagement is £5k under budget as are our Media Monitoring costs of £7k where we have found a cheaper supplier than budgeted for.

d. Our legal and professional fees have exceeded budget £32k due to unbudgeted legal costs for a case that was settled in quarter three of this year.

e. Consultancy where we charge our staff survey costs are under budget £5k due to profiling and our accommodation costs are over budget £9k due to an increase in service charges – mainly maintenance costs shared by all the tenants.
f. Non-cash costs (£39k) which relate to the depreciation/amortisation of our fixed assets; assets which we had budgeted to be deployed from April 2018 and which are yet to be deployed and therefore affects the year to date variance

Other key performance indicators

Debtors

24. At 31 December 2018, our outstanding debts total £271k represented by 47 organisations.

25. Below is a breakdown by sector of the outstanding debts as at 30 September 2018.

<table>
<thead>
<tr>
<th>Sector</th>
<th>Number of establishments</th>
<th>Value of debt (£)</th>
<th>%ge</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>30</td>
<td>196,411.25</td>
<td>72%</td>
</tr>
<tr>
<td>Government Bodies</td>
<td>1</td>
<td>13,039.47</td>
<td>5%</td>
</tr>
<tr>
<td>Non-Government Bodies</td>
<td>16</td>
<td>61,455.02</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>47</strong></td>
<td><strong>270,905.74</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

26. Of the total there are two organisations that have gone into liquidation with a total outstanding balance of £30k\(^1\). This has been provided for in the figures.

27. From our September billing run, there are accounts outstanding of £171k represented by 25 accounts. The bulk of these are NHS Foundation Trusts. These accounts have been and will continue to be pursued. The delay appears to be caused by the absence of purchase order numbers which causes SBS (shared business service) to reject our invoices.

28. The Government Bodies value is represented by monies due from DHSC for a seconded employee invoiced in December.

\(^1\) Precious Cells £16k and Pharmacells £14k
Forecast Outturn

29. At the end of Q3, we have reviewed our planned expenditure and amended our year end forecast to reflect increased costs for legal advice relating to upcoming legislative changes and exit from the European Union.

30. Overall we are forecasting a surplus against budget of £80k represented by an increase in income £242k by including non-cash income received from DHSC in the form of Ring-fenced RDEL, against an overspend on revenue expenditure of £162k. See table 4 below.

Table Four: Forecast Outturn – December 2018

For the Nine Months Ending 31 December 2018

<table>
<thead>
<tr>
<th>OUT TURN</th>
<th>Forecast</th>
<th>Budget</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>£</td>
<td>£</td>
<td>£</td>
<td>%</td>
</tr>
<tr>
<td>INCOME &amp; EXPENDITURE SUMMARY</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>(5,095,187)</td>
<td>(4,853,588)</td>
<td>(241,599)</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditure</td>
<td>4,998,407</td>
<td>4,836,835</td>
<td>161,573</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(96,780)</td>
<td>(16,753)</td>
<td>(80,027)</td>
</tr>
</tbody>
</table>

31. A further review of plans has been undertaken by SMT and it was agreed that directorates submit proposals for spending provided they can be achieved by March 2019. The forecast expenditure takes this into account.

32. A recent directive from DHSC will have an impact on the above and future spending as all ALBs have been tasked with making savings by not committing to any discretionary expenditure. Some of our forecast costs may therefore not be incurred. Our proposal is to delay c£80k of spending.

Financial risks

33. Financial risks are monitored on an ongoing basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – is currently rag status yellow as we
have a challenging budget due to a small decline in licence fee income. As of Q3, we are forecasting an underspend which may move by the end of the year.

**Table Five: 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 and quarterly re-forecasting. Review of activities that can be deferred.</td>
</tr>
<tr>
<td>Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income.</td>
<td>Periodic review of establishments and expected income. Budgets are then managed to reflect income.</td>
</tr>
</tbody>
</table>

**Business technology and working environment**

**Business technology**

34. The rollout of the new laptops has now been completed.

35. Additional IT resource has been procured to facilitate the CRM upgrade work. Testing is ongoing, in line with our high level plan, and to date no significant issues have arisen. There is the potential for developer resource availability to impact on timelines, and appropriate mitigations have been considered.

36. Annual Activity reporting functionality for the Human Application sector was developed on the HTA portal during December and launched on time in January.

37. The BCC on-site support position has now been filled. This role will be assuming additional responsibilities from the Head of Business Technology (HoBT) to alleviate some of the identified resource pressures and allow the HoBT to dedicate more time to the transformation programme.

**Delivery KPI narrative**

**Performance against 2018/19 KPIs**

38. Deployment KPI 12 Retention initiatives was marked as red in December. 65% of RMs had more than one year of service, against a target of 80%.

39. All other Deployment KPIs for quarter two are within target or tolerance and marked as green.
Code of Practice for Deemed Consent in England

Purpose of paper

1. To provide the Authority with an update on progress with amending our Codes of Practice in preparation for the introduction of deemed consent in England.

Decision-making to date

2. The Authority considered the proposed project plan at its meeting on 8 November 2018. This paper provides an update on progress to date.

3. The CEO approved this paper on 31 January 2018 for submission to the Authority.

Action required

4. Members are asked to note the content of this paper and to provide feedback on the structure of the draft Code of Practice F. Members will be asked to provide comments on the content of Code F by correspondence in quarter four.

Background

Legislative update

5. The Organ Donation (Deemed Consent) Bill 2017-19 (the Bill) intends to amend the interpretation of ‘appropriate consent’ set out in the Human Tissue Act 2004 (HT Act) to mean that where a person has not made a decision regarding organ donation during their life, or appointed a representative for this purpose, then consent may be deemed.
The Bill will only apply to deceased donation in England, and as drafted would apply to organs, tissues and cells for transplantation.

6. Members will recall that the Bill places a duty on the HTA to provide practical guidance on deemed consent, which will be by way of amended Codes of Practice.

7. The Bill had its second reading in the House of Lords on 23 November 2018. Following second reading, the following amendments have been tabled for consideration at Committee stage:

a. *The consent of the person is only deemed once a person in a qualifying relationship affirms that the person concerned would not have objected to the activity.*

b. *The Secretary of State to lay a report in the Parliament once in every five year period to review the effectiveness of deemed consent in increasing the number of organ and tissue donations.*

c. *The Secretary of State has the duty to explain deemed consent to the public and must promote awareness of the circumstances where consent to transplantation activities in deemed and the role of relatives and friends in affirming that deemed consent. This duty includes duty to inform the public through an advertising campaign at least once a year.*

8. The Committee stage is currently scheduled for 1 February 2019.

9. Subject to Parliamentary process, the Bill could receive Royal Assent as early as March 2019 with a public communications campaign planned to begin from April 2019.

10. The Bill, amended Codes of Practice, and further regulations, which set out material for which consent cannot be deemed, are currently planned for implementation from April 2020.

**Project Governance**

11. The project progress and key milestones are discussed in HTAMG on a monthly basis as a Development KPI on the HTA business plan.

12. Work is currently focussed on the amendments required to Code F – Donation of solid organs and tissue for transplantation. An initial draft of the Code is provided in Annex B to indicate the extent of the changes required. Specialist advice on drafting has been sought from professionals including Welsh Transplant colleagues, SNODs, NHSBT ODR team, Intensivists and DHSC as needed.
13. The project board membership includes the Head of Education and professional development (NHSBT) and the Head of Department, East Grinstead Eye Bank (non-NHSBT tissue bank), to ensure practitioner (user) views are reflected in the Code.

The Code of Practice F

14. The amendments to the draft Code are in progress. The Code will provide practical guidance on the circumstances in which the person concerned is to be deemed to have consented to organ and tissue donation in England.

15. The Code will be divided into three main sections:
   a. living organ donation;
   b. express consent for deceased organ and tissue donation;
   c. deemed consent for deceased organ and tissue donation.

16. The first section provides guidance to clinicians working in living organ donation and HTA Independent Assessors (IAs). This section will not be affected by the introduction of deemed consent.

17. The second and third sections provide guidance to SN-ODs, Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. A visual representation of how the sections of the code will apply is provided in Annex A. An initial draft of the Code to demonstrate how it will be structured is provided in Annex B.

18. Faith and cultural considerations, and the role of the family, have been highlighted as key issues in the Parliamentary debates. Work is ongoing to draft the relevant sections for the Code, which will be informed by close engagement with relevant stakeholders. Case studies will be added to help professionals facilitate the conversation in the most sensitive manner.

19. The Code will also be updated with amendments made to the Organ Donor Register, including the recently introduced 'faith declaration', and interpretation of new terms introduced by the Bill i.e. excepted adult, ordinarily resident and reasonable person.

20. The Code will be subject to change if the proposed amendments to the Bill are accepted.

21. In addition, minor amendments will required to Codes of Practice A, B, C, D, E and G to reflect the amendments to the HT Act. Minor updates will also be made to the Code of Practice on the Human Transplantation (Wales) Act 2013 to reflect the changes introduced by the Bill.
22. The tentative timeframe for preparing the Code of Practice remains as follows (subject to the Bill receiving Royal Assent in March 2019).

<table>
<thead>
<tr>
<th>Indicative Month</th>
<th>Milestone / task</th>
</tr>
</thead>
</table>
| October 2018 – March 2019 | First stage of amending Codes of Practice (A and F), changes to other Codes of Practice and amends to the Welsh Code of Practice  
Engagement with NHSBT, key stakeholders, faith groups etc. |
| April 2019             | Revisions to the Code of Practice if required following finalisation of legislation                                                                |
| April 2019             | Proof-reading and consistency check; Design and typesetting.                                                                                      |
| May 2019               | HTA and DHSC legal review                                                                                                                       |
| May - August 2019      | Stakeholder consultation on Code of Practice                                                                                                      |
| September 2019         | Analysis of consultation responses; Publication of response to consultation; Post-consultation amendments to be made to draft Codes; Proof-reading and consistency check |
| September 2019         | Second HTA and DHSC legal review                                                                                                                   |
| October 2019           | Design and typesetting                                                                                                                          |
| October 2019           | Draft Codes to Minister                                                                                                                        |
| October 2019           | All amended Codes of Practice to be laid before Parliament following summer recess (dates for summer recess not yet published on Parliament website).  
Welsh Code of Practice laid in Welsh Assembly (if required) |
| November 2019          | End of 40 day period                                                                                                                            |
| November 2019          | Final design and proof reading                                                                                                                   |
| October 2019 – March 2020 | Development of SNODs, CLODs, and Practitioners training plan by NHSBT and non-NHSBT affected stakeholders such as heart valve, eye and tissue banks.  
Extent of HTA's involvement to be agreed. |
| April 2020             | Post-implementation – HTA role as superintendent                                                                                                 |

**Stakeholder Engagement**

23. In quarter three we sent out a short survey to religious and cultural groups to gather initial feedback on their understanding and views in relation to the proposed deemed consent legislation.
24. We also held a number of meetings and conversations with key stakeholders across the system and those who have an interest in this area to assist our planning for engagement work in quarter four and beyond.

25. The survey also gave individuals a chance to register their interest in attending a roundtable event on deemed consent. This event is taking place on Monday 25 February in Westminster, London.

26. A more formal 12 week public consultation on the development of the Code will take place in spring/summer 2019.
This Code F schematic shows consent decision tree when the donor is an adult. When the donor is a child, consent cannot be deemed in England. The practitioners will follow the guidance for express consent in both Northern Ireland and England.
Code F: Donation of solid organs and tissue for transplantation

This is a draft working document intended to illustrate how the Code of Practice may be restructured to include the provisions for deemed consent in England.

Text highlighted in red has been added to illustrate amendments, including text which may be adapted from the Welsh Code of Practice. This text is only intended to be an example at this time.
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<td>22</td>
</tr>
<tr>
<td>The recipient interview</td>
<td>23</td>
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<td>23</td>
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<td>24</td>
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Introduction to the Human Tissue Authority Codes of Practice

1. The Human Tissue Authority’s (HTA) regulatory remit is defined in the Human Tissue Act 2004 (HT Act). The HTA regulates the following activities through licensing:
   
a) post-mortem examination;
b) anatomical examination;
c) public display of tissue from the deceased; and
d) the removal and storage of human tissue for a range of purposes, including research, medical treatment, education and training.

2. The HTA also assesses applications for organ, bone marrow and peripheral blood stem cell (PBSC) donations from living people.

3. Further information about the legislative background and context of the HTA and its Codes of Practice (including geographic coverage) is set out at Annex A.

4. This document is part of a suite of Codes of Practice produced by the HTA. The Codes give practical guidance to professionals carrying out activities which lie within the HTA’s remit under the HT Act and the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations). They will also be of interest to members of the public.

5. The HTA Codes of Practice provide guidance on activities within the scope of the HTA’s remit. Whilst the HTA may offer advice on matters outside its remit, it has no power to act in relation to these and will endeavour to provide signposts to other agencies where issues arise that are beyond its regulatory reach.

6. HTA Code A: Guiding principles and the fundamental principle of consent contains information that is applicable to all establishments and professionals operating under the HT Act and the Regulations. It sets out the following four guiding principles, which should inform the actions of anyone undertaking activities falling within the remit of the HTA:

   a) consent;
b) dignity;
c) quality; and
d) honesty and openness.
7. With regard to organ and tissue donation, this means donated organs and tissue must be used in accordance with the consent in place, that donors and their relatives must be given the information they need to be able to make a decision that is right for them and that those seeking consent should do so with sensitivity and an appreciation of the particular circumstances in each case. It also means that the dignity of the donor must be respected at all times and that practitioners should work with proper skill, care and training, in accordance with good practice and other relevant professional guidance.

8. This Code is divided into three main sections:
   a) Part 1 - living organ donation
   b) Part 2(a) - express consent for deceased organ and tissue donation
   c) Part 2(b) - deemed consent for deceased organ and tissue donation.

   The first section provides supplementary guidance to clinicians working in living organ donation and HTA Independent Assessors (IAs). The second and third sections provide supplementary guidance to Specialist Nurses - Organ Donation (SN-ODs), Specialist Requesters (SR), Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. See also paragraphs XX-XX.

9. In combination, Code A and this Code aim to support organ donation and transplantation where valid consent is in place by providing anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation and HTA policy.

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1 In England, it is lawful for consent for deceased organ donation to be ‘deemed’ in certain circumstances. See paragraphs xx-xx.
2 Throughout the Codes, the term ‘relatives’ should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act, details of which can be found at paragraphs xx-xx of Code A.
Introduction to the Donation of solid organs and tissue for transplantation Code

Scope of this Code

10. Living organ donation requires donor consent and HTA approval to be in place before a donation can proceed. The law requires that appropriate consent is in place in order to remove, store and use organs and tissue from living donors for transplantation. Once this consent has been obtained it remains an offence under the HT Act to remove an organ from a living person for the purpose of transplantation unless the HTA gives permission. This Code advises practitioners on the circumstances under which the prohibition on living donation can be lifted and HTA approval given. The process of living tissue donation itself does not require HTA approval and is therefore not within the scope of this Code.

11. For the purposes of living donation, HTA approval is required for the removal of an organ, or part of an organ (if it is to be used for the same purpose as the entire organ in the human body), where the intention is that it will be transplanted into another person. HTA approval is also required before an organ, or part organ, that is removed in this way can be used.

12. In deceased donation, the removal, storage and use of organs and tissue for transplantation is governed by the HT Act, this includes Vascularised Composite Allografts. Before organs and tissue can be removed, stored or used for transplantation, appropriate consent must be obtained. This Code advises practitioners on meeting the necessary consent provisions for this activity to be undertaken lawfully.

13. In England, the Organ Donation (Deemed Consent) Act 2019 (the Deemed Consent Act) modifies the appropriate consent provisions for organ donation and transplantation after death such that consent can be deemed in certain circumstances. Further guidance is given in Part 2(b) of this Code.

14. In Northern Ireland, the Deemed Consent Act does not apply, and practitioners should follow the guidance for express consent in Part 2(a) of this Code.

15. In Wales, the Human Transplantation (Wales) Act introduced deemed consent for deceased organ and tissue donation in 2013. Practitioners in Wales should continue to follow the Code of Practice on the Human Transplantation (Wales) Act 2013 [insert link].
16. In Scotland, the governing legislation on authorisation is the Human Tissue (Scotland) Act 2006. Further guidance on authorisation in Scotland can be found here [insert link].

17. In addition to the consent requirements above, establishments may also be subject to the licensing requirements of both the HT Act and the The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q & S (Organ) Regulations). This Code does not include detailed information on the Q & S (Organ) Regulations - further information can be found in Annex A paragraphs 6-7 and the HTA publication 'The Quality and Safety of Organs Intended for Transplantation – a documentary framework’. Further information on the licensing requirements under the HT Act can be found in paragraphs XX-XX.
Offences under the HT Act

18. The HT Act sets out a number of offences, for which the maximum penalty is imprisonment and/or a fine. In relation to organ and tissue donation, the offences are as set out below.

19. Section 5 of the HT Act makes it an offence to remove relevant material from the deceased and to store and use bodies and relevant material for a purpose set out in Schedule 1 of the HT Act (a scheduled purpose), including determining the cause of death, without appropriate consent. Where there is consent to use material for one purpose, it may not be used for another purpose without appropriate consent for that purpose. Section 5 of the HT Act also makes it an offence to falsely represent that there is appropriate consent to undertake an activity, or that Section 1 of the HT Act does not apply. A person does not commit an offence if they reasonably believed that appropriate consent was in place, or that the activity carried out was not one that required consent.

20. Section 8 of the HTA Act makes it an offence to store or use donated material for anything other than a qualifying purpose.

21. Section 32 of the HT Act makes it an offence to engage in commercial dealings in human material for transplantation (see paragraphs xx-xx).

22. Transplants involving live donors are illegal under section 33 of the HT Act unless the requirements set out in the Regulations are met (see paragraphs xx-xx).

23. Section 34 creates an offence of failing to comply with the Regulations made under this section, and failing to supply, or knowingly or recklessly supplying, false or misleading information about transplant operations. This offence is subject to a fine only.

Legal considerations - Conditions on consent for organ transplantation

24. Consent may be limited in a variety of ways. The HT Act does not prevent an individual from placing limits on their consent via the imposition of conditions, for example, to particular research studies or to donate specific organs.

25. The HT Act recognises that individuals have the autonomous right to give or refuse consent to all or any of their organs or tissue being used for transplantation after their death and for some organs, or tissue, to be used for transplantation while they are alive.
26. In law, individuals may also limit their consent by identifying a named recipient of an organ for transplantation, either as part of living donation, or for donation after their death. This is referred to as a directed donation.

27. No organ should be transplanted under a form of consent which seeks to impose restrictions on the class of recipient of the organ, including any restriction based on a recipient's gender, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status (including characteristics protected under the Equality Act 2010). This position reflects Article 14 of the European Convention on Human Rights, as set out in the Human Rights Act 1998, and arises from the equality duty placed on the HTA and other public authorities by the Equality Act 2010.

28. NHS Blood and Transplant (NHSBT) is the body that has legal responsibility for organ allocation across the UK and, as a matter of policy, does not accept organs from deceased donors where any condition is attached. However, requested allocation of a deceased donor organ can be considered if this is carried out in line with NHSBT policy [link].

29. It would be an offence to proceed with an activity for a scheduled purpose in the knowledge that a persisting condition on consent could or would not be fulfilled, as valid consent would not be in place. Only the person who has attached the condition to the consent can put the condition aside.

Structure and navigation

30. As noted above, this Code is divided into three main sections: living organ donation, express consent for deceased organ and tissue donation, and deemed consent for deceased organ and tissue donation. The first section provides supplementary guidance to clinicians working in living organ donation and HTA Independent Assessors (IAs). The second and third sections provide supplementary guidance to SN-ODs, Tissue Donor Coordinators, and others who seek consent for deceased organ and tissue donation. See also paragraph X.

31. A glossary with terms specific to this Code is available at the end of the document. You can view, download and print copies of all the Codes from the HTA’s website.
Part 1 - Living organ donation

Types of living organ donation

32. The HT Act and the Regulations place an obligation on the HTA to assess all referrals for living organ donation that are submitted. The HTA distinguishes a number of different concepts in living organ donation. These concepts, which are defined in the glossary, are: directed donation; directed altruistic donation; non-directed altruistic donation; paired and pooled donation; non-directed altruistic donor chains, and domino donation.

Legal considerations

33. The law requires that valid consent is required in order to remove, store and use organs from living donors for transplantation. Where consent has been obtained for the removal, storage and use of an organ, it is illegal to proceed with the living donor transplant unless the requirements of the HT Act and Regulations have been met. Therefore, in addition to securing valid consent, practitioners also require HTA approval before proceeding with the removal and use of organs for transplantation from the living.

Example

A clinician has obtained consent from a potential living donor for the removal, storage and use of his kidney for living donor transplantation to the donor’s sister. However, it is not legal to proceed without HTA approval and the clinician must refer the case to the HTA for decision via an Independent Assessor.

34. The HT Act governs the consent requirements for the storage and use of organs or part organs taken from a living person for the purpose of transplantation.

35. Consent for the removal of organs from living donors, whether for transplantation or otherwise, is covered by the common law and the Mental Capacity Act 2005 (MC Act), where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health’s Reference guide to consent for examination or treatment. Guidance for healthcare professionals in Wales is available in the Welsh Government’s guidance on Patient Consent to Examination and Treatment. The MC Act does not apply in Northern Ireland; further information about the law on mental capacity in Northern Ireland is provided in paragraphs xx-xx.
36. The requirements for living donor transplantation are set out in sections 33 and 34 of the HT Act and sections 9–14 of the Regulations. They require that donations of organs or part organs, with the exception of domino donations (see paragraph xx), must be approved by the HTA. The Regulations include the requirement that the HTA is satisfied that consent for removal of the organ has been given, or the removal is otherwise lawful (for example, it has been sanctioned by the Court).

37. The law allows a living donor to request that their donation be directed to any identified individual, regardless of whether or not he or she has a relationship (genetic or otherwise) with the intended recipient. It is not an offence to advertise, either via traditional or social media, to find a suitable donor. It is, however, an offence to offer a reward as part of any such advertisement (see paragraphs xx-xx).

38. Domino donation is a form of living donation where an organ or part organ is removed for the primary purpose of a person’s medical treatment, for example, where a heart is removed as part of a person’s medical treatment and the patient consents to the organ being offered for transplantation (for example, a heart originally removed from the recipient of a heart and lung transplant). While consent for use of the organ for transplantation does fall under the consent requirements of the HT Act, the donation would not be subject to the regulatory requirements which apply to other types of living donation (see paragraphs xx-xx) therefore HTA approval is not required.

Requirements for HTA approval to be given

39. Before the HTA can approve living donation cases, a registered medical practitioner with clinical responsibility for the donor must have arranged to refer the case to the HTA. The Regulations require that the HTA must be satisfied that:

a) no reward has been, or is to be, given (reasonable expenses can be reimbursed please see paragraphs xx-xx);

b) consent to removal for the purpose of transplantation has been given (or removal for that purpose is otherwise lawful);

c) an IA (see paragraphs xx-xx) has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient, and submitted a report of their assessment to the HTA. A donor interview is still required in situations where he or she is not able to give consent.

40. A person is qualified to conduct such an interview if:
a) they meet the HTA’s person specification for becoming an IA and have completed the approved HTA training and enhanced training where the circumstances of the case call for this (for more information on enhanced training please refer to the Guidance to transplant teams and Independent Assessors and paragraphs xx and xxx below);
b) they do not have any connection to those being interviewed, or their families, of a kind which the HTA considers might raise doubts about impartiality;
c) in the case of an interview with the donor (and any interview with another person giving consent), the IA is not the same person who gave them information about the procedure and its risks.

41. The Regulations also specify the matters to be covered in the report submitted by the IA to the HTA. For every interview the IA must report:

   a) whether there is any evidence of duress or coercion affecting the decision to give consent;
   b) whether there is any evidence of an offer of a reward;
   c) whether there were any difficulties in communicating with the person interviewed (e.g. language, hearing), and if so, an explanation of how these difficulties were overcome.

42. In addition, for interviews with the donor (and any interview with another person giving consent), the following must be provided:

   a) the information given to the person interviewed as to the nature of the medical procedure and the risk involved;
   b) the full name of the person who gave that information to the person interviewed, and their qualification to give it;
   c) the capacity of the person interviewed to understand the nature of the medical procedure and the risk involved and to understand that consent may be withdrawn at any time before the removal of the transplantable material.

43. A donor or recipient, a person acting on behalf of either, or the registered medical practitioner who caused the matter to be referred to the HTA, may ask for a review of any decision on a case made by the HTA. The process for doing this is laid out within the Regulations and requires a fresh decision to be made by the HTA.

**Commercial dealings in human material for transplantation**

44. The HTA requires that checks are made to ensure that no reward has been given, or is to be given, for the donation. However, the HT Act allows donors to
receive reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation. Further information on reimbursement arrangements is available in NHS England’s policy on Reimbursement of Expenses for Living Kidney Donors in England and the Welsh Government’s Specialised Services Policy on Live Donor Expenses for living donors in Wales. Guidance in Northern Ireland was being developed at the time of drafting this Code.

45. Where reimbursement is not made by the NHS, nothing in law prevents a recipient (or the family of the recipient) from directly reimbursing the donor’s expenses. In this circumstance, the donor and recipient should provide evidence to prove that the donor has not materially benefitted in any way, for example that only directly attributable costs were paid.

46. The HT Act also prohibits commercial dealings in human material, including organs or tissue, for the purposes of transplantation. A person is committing an offence if they:

a) give, offer or receive any reward (financial or other material advantage) for the supply or offer of supply of any organ or part organ;
b) look for a person willing to supply any organ or part organ for reward;
c) offer to supply any organ or part organ for reward;
d) initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any organ or part organ;
e) take part in the management or control of any type of group whose activities consist of or includes the initiation or negotiation of such arrangements;
f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any organ or part organ for reward, or indicating that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media. For further information please see the guidance on matching websites and social media on the HTA website and the NHSBT guidance on social media and living donation.

47. This offence, outlined in paragraph xx, carries the risk of a fine and up to three years imprisonment. No offence is committed, however, where payments relate to reimbursement of the donor’s expenses, or where reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.
Donation by children

48. Children can be considered as living organ donors only in extremely rare circumstances. The HT Act defines a child as being under 18 years old. If a clinician intends to consider a child as a living organ donor, they are advised to discuss the case with the HTA at the earliest opportunity.

49. In accordance with common law and the Children Act 1989 (which established the legal basis for who has parental responsibility), court approval should be obtained before the removal of a solid organ or part organ from a child for donation. Transplant Units should obtain their own legal advice regarding seeking court approval.

50. Living donation by a child under the HT Act can only go ahead with the approval of an HTA panel. Such cases must only be referred to the HTA for decision after court approval for the removal has been obtained.

Donation by adults lacking capacity to consent

51. The HT Act does not specify the criteria for considering whether an adult has capacity to consent. Under the MCA Act, a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

a) understand the information given to them that is relevant to the decision;

b) retain that information long enough to be able to make the decision;

c) use or weigh up the information as part of the decision-making process;

d) communicate their decision by any means.

52. Full guidance on how the MCA Act defines capacity and how it should be assessed are given in chapter 4 of the MCA Act Code of Practice.

53. The provisions of the MCA Act should be considered together with general principles governing capacity to consent to medical procedures. Further information is available from the Office of the Public Guardian website and in the MCA Act Code of Practice. The Welsh Government has published separate guidance for Wales.

54. The MCA Act defines persons who lack capacity and contains a set of key principles and a checklist to be used in ascertaining best interests. The first core principle of the MCA Act is that an adult must be assumed to have capacity

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3 See chapter 4 of the MCA Act Code of Practice.
4 See chapter 5 of the MCA Act Code of Practice.
to make a decision for themselves, unless it is established that they lack capacity to make the particular decision at the time the decision needs to be made.

Assessing capacity to consent in Northern Ireland

55. The MC Act does not apply in Northern Ireland. The Mental Health Order 1986 covers the assessment, treatment and rights of children and adults with a mental health condition who may need to be admitted to hospital for assessment in treatment. Common law is used to assess the capacity of adults and children. A mental health and capacity bill has been drafted for Northern Ireland, but it was not in effect at the time this Code was published.

56. The Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI) published its own reference guide to consent for examination, treatment or care in 2003. This guidance is based on mental health and capacity case law. Each of the five regional Health and Social Care Trusts has published its own policy on the assessment of mental capacity, based on the 2003 departmental guidance. These policies draw on the MC Act, with regards to its principles, the assessment of mental capacity and the best interests test. People are presumed to have capacity to make decisions unless it is established that they do not.

57. Advance decisions⁵ are made in Northern Ireland under common law and the 2003 departmental guidance, but these decisions are not legally binding under any statute. Enduring Powers of Attorney can be established under The Enduring Power of Attorney (Northern Ireland) Order 1987, but their decision-making powers are limited to financial matters and do not extend to welfare.

58. There is no Court of Protection in Northern Ireland, and therefore there are no Welfare Deputies; applications for decisions on welfare matters involving children and adults who have been found to lack capacity under common law and departmental guidance are made to the High Court.

Requirements for court approval for adults lacking capacity in England and Wales

59. The HT Act makes no provision for appropriate consent for the removal of material from a living adult who lacks capacity to consent for himself or herself.

⁵ A decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future, including the refusal of organ, bone marrow or peripheral blood stem cell donation.
A lawful decision to give or refuse consent on behalf of an adult who lacks capacity can only be made through one of four routes:

a) by an Advance Decision made by the donor to refuse consent for the proposed treatment which covers this type of donation and was made at the time when the donor had capacity. If such an Advance Decision is in place then no Court can override that decision and lawful consent will never be given;

b) by the donor executing a valid Lasting Power of Attorney (LPA), giving another person power to make this type of decision. The LPA must have been made by the donor at a time when the donor had capacity (see section 9 of the MC Act);

c) By a person who has been given the power to make such a decision when appointed as welfare deputy by the Court of Protection (see section 16(2)(b) of the MC Act). The HTA considers that a welfare deputy should not rely on a general welfare power to make these decisions but should only rely on his or her decision making power under the deputyship order if this is a matter where the power to give consent to organ donation has been specifically given to him or her; or

d) By a judge of the Court of Protection making a best interests decision on behalf of the adult lacking capacity (see section 16(2)(a) of the MC Act).

60. The Code of Practice for the MC Act states that, where an adult lacks the capacity to consent to the removal of an organ for transplantation, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and, following court approval, the case is referred to, and approved by, an HTA panel.

61. As the court is authorising the removal, there is no-one else providing consent on the donor’s behalf, and therefore only interviews with the donor and recipient can be undertaken.

62. Transplant Units should take their own legal advice regarding how to seek appropriate court approval.

63. If a clinician intends to consider an adult lacking capacity as a living organ donor, they are advised to discuss the case with the HTA at the earliest opportunity.

Guidance for Clinicians and Transplant Teams
64. Clinicians and transplant teams are responsible for the overall care of donors and recipients, and for assessing the medical suitability of potential donors. The decision about whether a person is medically fit and clinically suitable as a living organ donor is a matter for the practitioners concerned. The British Transplantation Society (BTS) has published guidance for clinicians entitled *United Kingdom guidelines for living donor kidney transplantation* and the *United Kingdom guidelines for living donor liver transplantation*.

65. While the HTA provides advice on how our regulatory requirements will apply to individual cases, the decision on whether to work up a case rests with the transplant unit.

66. All potential donors should be provided with a copy of the HTA leaflet *Our role in living organ donation* and the HTA Guidance for living organ donors on the Human Tissue Authority’s independent assessment process at an early stage in the work-up process to ensure that they understand the way in which living donation is regulated and how this will affect them. They should also be provided with a copy of the donor declaration form relating to reward for organ donation which is to be signed by the donor either before or at the IA interview. This form is available in multiple languages on the HTA website.

**Securing valid consent**

67. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Clinicians have the responsibility of ensuring that valid consent to the removal, storage and use of organs or part organs is in place prior to referral to the HTA. Part of the HTA’s role is to act as an independent check that legally valid consent is in place.

68. The HT Act requires that consent be obtained to store and use organs for transplantation. Consent for removal is governed under common law, but the HTA has the regulatory role of ensuring that valid consent for removal is in place. The necessary consents should ideally be sought in a single process.

69. While it is not a legal requirement, it is best practice to obtain written consent for significant procedures such as organ and tissue donation. When consent is obtained but is not in writing, this should be clearly documented in the patient’s records. The record should detail when consent was obtained and the purposes for which it was given.

70. In situations where adult patients lack capacity, a consent form for adults who are unable to consent to investigation or treatment should be completed. More
Ensuring the donor gives informed consent

71. Potential donors must be provided with sufficient information to reach an informed decision about whether they wish to donate an organ. This information must be provided by the transplant team before the IA interview.

72. If a donor lacks the capacity to consent, it is recommended that contact is made with the HTA early on during the workup in order that specific advice can be provided. See further information at paragraphs xx-xx.

73. It is important that the donor is advised that they will need to provide consent to both the surgical procedure under common law, and the use of the organ for the purpose of transplantation under the HT Act.

74. To ensure that the informed consent of the donor is secured, the transplant team must make sure the following areas are discussed with the donor:

a) the nature of the surgical/medical procedure and medical treatments involved for the donor, and any material short and long term risks (this should be explained by a medical practitioner with appropriate qualifications to give this information). A material risk is where, in the circumstances, a reasonable person in the donor’s position would be likely to attach significance to the risk, or the transplant team is or should be reasonably aware that the donor would be likely to attach significance to it. This information should include the risk of death to the donor (see paragraph x of Code A for further information on the relevant case law);

b) the chances of the transplant being successful, and any significant side effects or complications for the recipient, and in particular the donor should be made aware of the possibility of graft failure in the recipient;

c) the right to withdraw consent at any time before the removal of the transplantable material;

d) that the decision to donate must be free of duress or coercion;

e) that it is an offence to give or receive a reward for the supply of, or for an offer to supply, any organ. It is also an offence to seek to find a person willing to supply any organ for reward. If found guilty of this offence a person may face up to three years in prison, a fine, or both.

75. The donor must have a clear understanding of the benefits and disadvantages of living donor transplantation in their particular case, as well as the general
risks and benefits. Further information on this can be found in the BTS document *UK Guidelines for living donor kidney transplantation* and the BTS *UK Guidelines for living donor liver transplantation*.

**Additional information for potential non-directed altruistic and paired/pooled organ donors**

76. For potential non-directed altruistic and paired/pooled donors, the donor must also be informed of how the altruistic, paired/pooled process works, and how a suitable recipient, or in the case of paired/pooled donation, suitable matches, are identified.

77. The donor must also be informed that anonymity of the donor and recipient is required before the operations, and that confidentiality must be respected.

78. Further information on these types of transplantation is available on the NHS Blood and Transplant (NHSBT) website.

**Referring cases to the HTA**

79. The Regulations require that a medical practitioner with clinical responsibility for the donor must have caused the matter to be referred to the Authority. Certain specified information is required from the referring clinician as part of this referral where it concerns an organ. Specifically, the referral must state that the medical practitioner, or person acting under their supervision is satisfied that the donor’s health and medical history are suitable for the purposes of donation, and has:

   a) provided the donor with the information the donor requires to understand the consequences of donation;
   b) endeavoured to obtain information from the donor that is relevant to transplantation.

80. As a matter of HTA policy, the HTA requests that referring donor clinicians also state that the medical practitioner is satisfied that the donor has capacity to consent to the donation. It is also requested that detail is provided on the recipient’s capacity to participate in an interview to allow the IA to make any necessary adjustments. The HTA has created a model referral letter template for units to use to ensure that all the legislative requirements are addressed in the referral letter to the HTA. The HTA cannot make an assessment until it has received the referral letter.
81. Arrangements for the statutory interview can be made at the point at which the referral letter is received by an appropriately trained IA. It is important that, if the circumstances of the case require it, the referral is made to an IA who has received enhanced training (see paragraph x). A list of these IAs is available from the HTA.

82. Transplant teams should ensure that they factor in sufficient time for both the IA interview and HTA process to be completed, when scheduling provisional surgery dates.

83. Where the donor is also the only suitable adult to accompany a child recipient to the IA interview, the transplant team is advised to contact the HTA’s Living Donation Assessment Team (LDAT) for further advice.

Guidance for Independent Assessors (IAs)

Accepting referrals

84. Before accepting a referral for a case, IAs should make sure that they will be able to:

   a) undertake the interview within one month of referral;
   b) submit their report to the HTA within 10 working days of the interview;
   c) be available in the five working days following the submission of their report, in case the LDAT needs to contact them for further information or clarification.

85. Where the IA is made aware of a shorter deadline for the assessment of a case, for example, where there is an urgent clinical need, they should consider the implications of this before accepting the referral.

86. It is important that annual leave arrangements are taken into account when scheduling interviews as delays may result in scheduled surgery not being able to proceed. If an IA considers they may not be able to undertake interviews, or submit reports within the above timescales, or they are on leave in the five days following submission to the HTA, it would be advisable to ask the transplant team to find an alternative IA for that case.

Statutory interviews

87. This section should be read in conjunction with the HTA Guidance to Transplant Teams and Independent Assessors, which provides detailed information on all aspects of the IA role, including who can become an IA and good practice guidance on undertaking interviews.
88. The Regulations require that an IA must have conducted separate interviews with the donor (and the person giving consent if this is not the donor) and the recipient. In addition, it is HTA policy that, in the case of directed donation, an interview must be undertaken with donor and recipient together. The purpose of this is to allow the IA to observe the interaction between the donor and recipient, to contribute towards an understanding of whether duress or coercion are likely to be factors in the donor’s decision to donate, and to explore the issue of reward jointly with the donor and recipient.

89. There may be rare circumstances where the donor and recipient do not wish to be interviewed together. In these cases the HTA must be contacted to make an application for the requirement for the joint interview to be withdrawn.

90. A recipient interview cannot be undertaken in cases of non-directed altruistic donation because there is no identified recipient at the time of the interview.

91. The Regulations detail the matters to be covered in the reports on the interviews to be submitted by IAs (described in paragraph x). As a matter of policy the report should also contain an account of any relevant concerns the IA has which should contribute to the Authority’s assessment of whether or not it is satisfied in relation to the legal tests described at paragraph x.

The donor interview

92. The interview with the donor must, by law, cover the matters described in paragraphs xx-xx.

93. The primary role of the HTA is to ensure that valid consent to the removal is in place. The IA report will need to address whether the donor has been placed under any duress or coercion to consent to the procedure. For the purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor, either by the recipient or a third party, to go ahead with the donation. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.

94. The IA report will need to address whether there is any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to either the donor or any third party, for example, to anyone acting as an intermediary to bring the donor and recipient together.
**The recipient interview**

95. The interview with the recipient must, by law, cover the matters described in paragraph xx.

96. In all cases the IA must undertake, or attempt to undertake, an interview with the recipient. The only exception is where the recipient unarguably lacks capacity, for example if they are a baby or a pre-verbal child then attempting an interview would be impossible. In such cases the IA should, as a minimum, see the recipient and report to the HTA on any communication difficulties, providing clear and detailed information on why an interview was not possible in the appropriate section of the report.

97. The IA report on the interview with the recipient must cover any evidence of duress and coercion affecting the decision to give consent. For the purposes of the interview, the IA should report evidence of any pressure which has been placed on the donor by the recipient to go ahead with the donation. In reaching a decision about whether this constitutes duress or coercion the HTA would need to make a judgement on whether the will of the person providing consent has been overborne such that they can no longer make an independent decision.

98. The recipient interview must also cover any evidence of reward. The HTA interprets this to mean any evidence of an offer of reward to the donor or a third party. Any reward might have been offered by the recipient, or by another party. Where it is not suitable to directly address financial reward with a child, a discussion on how the offer of donation arose could be considered.

**General advice on interviewing child recipients**

99. The IA interviews the potential donor and recipient to assess whether the HTA requirements have been met. Interviews should take place with the recipient at a level appropriate to their age and understanding.

100. There is no statutory provision for someone to be interviewed on the recipient’s behalf, so a recipient interview must be attempted. In cases where the recipient is at a stage of development where language or comprehension are limited, IAs should adopt an extremely light touch approach to assessing the issues of duress, coercion and reward, by exploring what the recipient knows about the procedure and their knowledge of how the donor came to be chosen to donate to them. It is good practice to involve the parent(s) in these discussions but there is no legal role for the parents to respond on behalf of the child.
101. Please see paragraph xx for further guidance on interviewing very young children.

Completing and submitting an application

102. The legal framework requires that the HTA, not the IA, make the decision on whether a case can proceed. In every case of living organ donation the HTA decision maker must have sufficient evidence to exercise an independent judgement on whether the legal tests relating to living donation are met. The primary source of evidence to exercise this judgement is the IA report. This means that the IA must provide a comprehensive account of their interviews including the rationale for any conclusions they draw and not only the conclusions themselves.

103. Following an interview, IAs should submit a report of their interview to the HTA within 10 working days. If for any reason the report cannot be submitted within 10 working days, the IA should inform both the transplant team and the HTA.

104. The IA report is a confidential document between an IA and the HTA. It is not appropriate to share any details of the report, or the report itself, with the clinical team.

105. A copy of the referral letter and donor declaration should also be submitted at the time of the report submission.

Requirements for Authority panel cases

106. The Authority has a legal obligation to assess all cases that are referred to it. Some cases can be delegated to a member of the HTA LDAT for a decision; other cases are assessed by a panel of three Authority Members (panel cases). The Authority currently distinguishes two types of panel case:

a) Authority panel cases mandated by law, as described in the Regulations;
b) Authority panel cases, where the Authority has decided as a matter of policy (rather than legal obligation) to retain decision making responsibility and not delegate to the LDAT.

107. Authority panel cases by law comprise situations where:

a) the donor is a child;
b) the donor is an adult lacking capacity to consent;
c) paired donations;
d) pooled donations;
e) non-directed altruistic donations.

108. Authority panel cases are decided by the level of regulatory risk associated with the circumstances of the case and are subject to change. The HTA Decision-Making Framework sets out which cases are retained and which are delegated.

109. Some panel cases require increased scrutiny and for independent assessments to be completed by an IA who has completed enhanced training. Cases which require an assessment by such an IA are included in the HTA’s policy on IA assessments and Guidance to Transplant Teams and Independent Assessors. IAs must ensure that they are only allocated cases which they have the necessary training to assess.

**HTA decision-making arrangements**

110. The HTA aims to make decisions within timeframes published each year in the HTA business plan.

111. Once a decision has been made by the HTA, an automated notification will be issued to the IA, Living Donor Coordinator(s) and the clinicians detailed in the report. Living Donor Coordinators must inform the donor and recipient of the decision on the HTA’s behalf.

112. In cases where the requirements have not been met and the HTA turns a case down, the donor (or someone acting on their behalf), recipient, and medical practitioner with responsibility for the donor will be notified in writing. The letter will also outline the procedure for reconsideration of the decision.

113. However there may be cases where the HTA decides that it would not be appropriate to provide full reasons or that doing so would breach another person’s rights under the Human Rights Act 1998 or would breach a duty of confidentiality owed to any person.

114. Detailed information on the way in which the HTA makes decisions can be found in the HTA Decision-Making Framework, its policy for the assessment of living organ donation cases and HTA Standard Operating Procedures, which are available on request from the HTA.
Part 2 - Deceased organ and tissue donation

General considerations

Further Legal considerations

115. This section should be read in conjunction with the National Institute for Health and Care Excellence (NICE) guidance on Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation. NICE recommends that organ donation should be considered as a usual part of end-of-life care planning.

116. The HTA’s remit is to provide guidance on what constitutes lawful consent to organ and tissue donation after death has been diagnosed, either using the brainstem death criteria or the circulatory death criteria. Diagnosis of death is a matter for clinicians providing end-of-life care.

117. For a patient with a life-threatening or life-limiting condition, the clinical team may, in discussion with the relatives, decide to withdraw life-sustaining treatment. This would usually be expected to result in circulatory death with the attendant possibility of donation after circulatory death (DCD). Where the patient lacks capacity, any decisions about the timing of withdrawal of life-sustaining treatment or the institution of new therapies or treatments to enable organ donation to proceed must be taken in the patient’s best interests. The patient’s known wishes with regard to organ and tissue donation, whether recorded or as expressed to relatives, are one factor to include in the assessment of the patient’s best interests. Any discussion with the relatives should be approached and discussed sensitively.

118. Further guidance on legal aspects of interventions before death in DCD cases is available in the Department of Health and Welsh Assembly Government’s guidance on Legal issues relevant to non-heart beating organ donation. The UK Donation Ethics Committee also publishes ethical guidance for clinicians on the same issue.
Deceased organ donation consent provisions overview

119. In all cases, the decision of the individual to either consent, or not to consent, to donation of organs or tissue for transplantation is paramount.

120. In England, the Deemed Consent Act modifies the appropriate consent provisions for organ donation and transplantation after death. This has the effect that where an adult who is ordinarily resident of England has not made a decision on organ and tissue donation, or appointed a nominated representative, then consent for donation of organs and tissues is deemed to have been given by the individual. However, it does not mandate that organ donation goes ahead in such cases.

121. If a person made a decision in regard to organ donation when they were alive, their consent cannot be deemed.

122. If a person appointed a representative/s to make a decision, their consent cannot be deemed. The decision of the appointed representative/s should be acted upon. If the appointed representative is unable to act, then the express consent of a person in a qualifying relationship or a person with parental responsibility (in the case of children) may be sought.

123. The Deemed Consent Act does not make any material amendments to the regulatory framework for living organ donation.

124. In Northern Ireland, the Deemed Consent Act does not apply. Practitioners should follow the guidance for express consent in paragraphs xx-xx.

Recording a decision about organ donation

125. The HT Act and Deemed Consent Act do not require that a person records their decision about organ and tissue donation in a specific manner.

126. This means that it is for the individual to decide how they wish to do this, and options include telling a friend or family member, recording it in writing and registering on the Organ Donor Register (ODR).
127. The ODR is checked in every potential case of organ and tissue donation after death and the information on it will be communicated by the SNOD to family and/or friends.

**Role of the family**

Insert:

- General information on the role of the family and how they can be sensitively supported;
- Signpost to specific information on the role of the family in both express and deemed consent situations.
Licensing under the HT Act

**HLA tissue typing**

128. If samples of relevant material from a deceased donor, such as blood, lymph nodes or spleen, are being stored for tissue typing to determine the suitability of an organ for a recipient, this is storage for the purpose of transplantation and excepted from licensing under the Human Tissue (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 if the material is stored for less than 48 hours. If those samples of relevant material are subsequently stored as part of the diagnostic archive of the recipient, a licence is not required. However, if such samples are subsequently stored for research within the scope of the HT Act, they must be stored on HTA-licensed premises, subject to any applicable licensing exemptions. Further guidance can be found in the HTA’s Code of Practice for Research.

** Licence requirements – Research**

129. A licence is required under the HT Act for the removal of relevant material from a deceased person for the scheduled purpose of research ‘in connection with disorders, or the functioning, of the human body’. The removal must take place on premises specified in the licence.

130. The storage of relevant material for the purpose of research also requires a licence, unless it is for a specific research project which is approved by a recognised research ethics committee.

131. If relevant material removed for the purpose of transplantation is subsequently used for research, rather than transplantation, the storage of this material must be premises specified in the licence unless the research has ethical approval as indicated above.

132. Relevant material removed for the purpose of transplantation can be used for research with the valid consent of the donor or a person in a qualifying relationship to the donor (see paragraphs 30-39 of Code A).

133. In cases where it is unknown whether donated tissue or organs will be used for transplantation or research, valid consent should be obtained at the outset for both transplantation and research. For further guidance on valid consent, refer to the Code of Practice on Guiding principles and the fundamental principle of consent.
134. Further guidance on both consent and licensing requirements for research can be found in the Code of Practice on Research. This guidance is applicable to cases involving research using tissue and organs from a deceased donor; the Code of Practice on Research also provides guidance on research using tissue from the living.
Part 2(a) - Express consent

Consent for organ donation – adults

135. The HT Act makes clear that where an adult made a decision to consent to organ donation taking place after their death, then that consent is sufficient for the activity to be lawful.

136. Similarly, where an adult made a decision not to consent to organ donation taking place after their death, then the activity must not proceed, as consent is not in place.

137. In cases of potential deceased donation, the SN-OD or delegated person should be approached to determine whether the potential donor had recorded their wishes with regard to organ donation via the ODR or whether a nominated representative had been appointed.

The Organ Donor Register as a source of consent

138. The Organ Donor Register (ODR) operates throughout the UK to allow individuals to record their wishes about organ and tissue donation after they have died. The ODR allows people to record whether they wish to donate all, some or no organs and tissue.

139. As long as a person registered their decision voluntarily, had the information they needed to make the decision to register and had mental capacity or competence when they registered, then the decision recorded on the ODR constitutes valid and appropriate consent at the time of registration.

140. The ODR allows the following decisions to be recorded:

   a) I consent to donate all my organs after death;
   b) I consent to donate some (specified) organs after death;
   c) I do not consent to donate my organs after death;
   d) I wish to appoint a representative to make a decision on organ donation after death on my behalf.

141. Individuals who do not wish to donate their organs and tissues are able to record their wish on the ODR. Those who do wish to donate are able to express their wish on the Register and select the organs they are willing to donate. Individuals will continue to be able to change or amend their decision at any time. The ODR also has the option to record if faith is important to an individual for organ donation decision and that family and/or a faith leader should be consulted if organ donation is a possibility after death, to ensure that any religious considerations are observed.
142. If the recorded decision was to donate some or all organs, and the family state that the person had changed their minds and did not wish to donate their organs, consideration will need to be given to the evidence presented (see paragraphs XX to XX).

Example/scenario:
SNOD approach to the family; considerations; steps to the decision.

143. If the recorded decision was not to be an organ donor then this can be communicated to the family. If the family state that the person had changed their mind and wanted to donate their organs, they must provide the SN-OD with the evidence they believe proves the person did make a decision to be an organ donor and that this decision supersedes their recorded decision not to donate.

144. If the SN-OD/SR accepts that the person has changed their mind, having previously recorded a decision not to consent on the ODR, then donation could go ahead.

145. A legally valid decision from the donor him or herself is sufficient to allow organs and tissue to be retrieved for transplantation where they have decided to donate. Similarly, in circumstances where they have decided not to donate, donation cannot proceed. There is no legal right for anyone in a qualifying relationship to revoke a legally valid decision to give or withhold consent.

Example
The prospective donor registered on the ODR her wish not to donate her heart. Unless evidence is provided that she had changed her mind since registering, this constitutes a legally valid decision to withhold consent and heart donation could not proceed. Relatives have no ability to overturn withheld consent.

146. If relatives or friends state that a prospective donor who was registered on the ODR no longer wished to be an organ or tissue donor, the SN-OD should ask for evidence to support this assertion. In making a decision about whether or not there is valid consent to proceed with donation, the SN-OD must make the judgement about how much weight to attribute to the evidence.
147. In order to assess the weight of the evidence presented, the following questions may be considered to aid the SN-OD in reaching a decision:

a) is the evidence in writing, signed and dated by the person and witnessed? If this is the case, then this is likely to form an express decision of the person (it is important to note that revocation of consent does not need to be written, merely that a written revocation may attract greater weight in decision making);

b) is the evidence oral? If so, is it corroborated by more than one person?;

c) is the evidence presented as reflecting the views of the person, or the views of the relatives presenting it? If the latter is the case, then this is likely to constitute an objection as opposed to evidence that the person had changed his or her mind.

148. Where valid consent has been given by the donor, but relatives object to organ or tissue donation proceeding, then they should be sensitively supported to respect the prospective donor’s consent to ensure his or her wishes are fulfilled. A relative’s objection does not nullify appropriate, valid consent from the prospective donor.

Example

A prospective donor has given valid consent to the donation of her organs for transplantation. Her son does not want the donation to proceed because he does not want organ retrieval to take place during a traumatic time for the wider family. The donor’s consent is still valid and retrieval could proceed. The son should be sensitively encouraged to support his mother’s wishes.

149. The existence of appropriate, valid consent permits an activity to proceed, but does not mandate that it must. The final decision about whether to proceed with the activity rests with the medical practitioner.

150. The HT Act establishes the principle that the decision to consent to the use of organs and tissue for transplantation after death rests first and foremost with the donor him or herself. As such, the donor’s valid consent where this is recorded, or known wishes as expressed to relatives, should form an integral part of end-of-life care planning.
Other sources of recording Consent

Nominated representative

151. If the deceased person’s decision is not known and they were an adult who had nominated a person to deal with the use of their body after death, then consent can be given by that nominated representative (see paragraphs XX – XX of Code A).

152. The name and contact details of the nominated representative/s may have been recorded on the ODR, and this is the first check the SN-OD should make. It is likely this will take place when the ODR check is being made as per paragraph XX. If there is a recorded nominated representative/s, the SNOD should contact them and ask them to make a decision on behalf of the person.

153. If the details of the nominated representative are on the ODR, the SNOD does not need to carry out the checks at paragraphs XX to XX.

154. If the nominated representative on the ODR cannot be contacted in time to make a decision, or is unwilling to make a decision, then a person in a qualifying relationship to the person concerned immediately before death may be approached to make a decision about organ donation, or a person with parental responsibility in the case of a child. The list of qualifying relationships will be ranked in accordance with paragraph XXXX.

155. If there is no decision recorded on the ODR, then the SNOD should make reasonable enquiries at the hospital, with the prospective donor’s GP or with those close to the deceased person to ask whether a nominated representative was appointed to make a decision on their behalf in regard to organ donation.

156. If the SNOD is informed that there is an nominated representative/s, the checks at paragraphs XX to XX below should be undertaken to ensure they have authority under the Human Tissue Act 2004.

157. If the nomination was made orally the SNOD needs to check that the appointment was witnessed by at least two people. This can be confirmed either by the two witnesses or in a document produced with the two people’s signatures confirming they witnessed the nomination.

158. If the nomination was made in writing, the SNOD should be assured that one of the statements at a to c below is true:

   a. The document making the nomination was signed by the person in the presence of a witness who confirmed the signature; or
b. It was signed by another person at the direction of and in the presence of the person, and in the presence of a witness who confirmed the signature; or

159. If more than one person has been nominated, unless the nomination provides that they are nominated to act only jointly, the default position is that the nominated representatives can make the decision jointly and separately. This means that the representatives do not have to agree, so one of them can give consent regardless of what the other representative(s) decide.

160. However, where the nomination provides that multiple representatives must act jointly. This means that all representatives must agree before consent can be established. In these circumstances, if one representative cannot be contacted then the other representatives cannot give consent.

161. It may be the case that a person nominates representative(s) but did not record them on the ODR or tell their family/friends about them. It is recognised that it is not practical for the SNOD to make numerous checks to establish whether a person nominated a representative/s. It is therefore considered adequate for a SNOD to check the ODR and to ask family/friends. It is important that a note is made of these checks and any discussions with family/friends.

162. A child cannot act as an nominated representative under the HT Act.

163. Further information on nominated representatives can be found in paragraphs XX–XX of Code A.

When there is no recorded decision or nominated representative(s)

164. Once the SNOD established that the person had not recorded a decision on the ODR or nominated a representative/s, they should ask the family/friends present or contactable whether they are aware of the person’s decision in regard to organ donation after death.

165. If the SNOD is informed that the person had recorded their decision in writing, but not on the ODR, the SNOD should seek to establish where that record is held and to gain a copy of it.

166. If the SNOD is informed that the person recorded their decision orally, the SNOD should speak with the person who was informed of the decision and make a note of the details of this conversation.
167. The SNOD will need to make a decision, based on the evidence presented to them, whether they are satisfied that this constitutes the person’s decision in life. It is considered that written, signed and dated evidence which was witnessed is most likely to satisfy the SNOD that this was the decision of the person in life.

168. This does not mean that other forms of evidence, such as oral evidence, will not satisfy a reasonable person, but rather that the SNOD must make a judgment as to whether it is reliable.

Qualifying relationships (Northern Ireland and England (excepted adults and children))

169. In Northern Ireland and for excepted adults, children and other excluded categories individuals in England, if the deceased person has not indicated their consent (or refusal) to the use of their organs for transplantation or, in the case of an adult, appointed a nominated representative, then the appropriate consent may be given by someone who was in a qualifying relationship with the deceased person immediately before their death.

170. An approach should be made to the deceased person’s spouse or partner, relatives or close friends (see paragraphs 30-39 of Code A on qualifying relationships) by a SNOD. Best practice recommends that the approach to the deceased person's relatives should be made together by the SNOD and a member of the team who is caring for the person to establish any known decision of the potential donor.

171. The HT Act includes at section 27(4), a list of qualifying relationships:

   a) Spouse, civil partner, or partner;
   b) Parent or child;
   c) Brother or sister;
   d) Grandparent or grandchild;
   e) Child of a brother or sister (niece or nephew);
   f) Stepfather or stepmother;
   g) Half-brother or half-sister; or
   h) Friend of long standing.

172. A person is another person’s partner if the two of them lived as partners in an enduring family relationship. Partner can be different genders or be of the same gender.
173. A friend of long standing is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD may ask questions and/or request evidence as necessary to establish what degree of friendship existed.

174. When there is disagreement between people in different positions on the ranked list, it is recommended that the SNOD seeks to provide those people with the time and information they need to come to an agreement.

175. If those close to the person object to the donation, for whatever purpose, when the person (or their appointed representative, see paragraphs XX to XX) has explicitly given their consent, or their consent can be deemed, the SNOD should seek to discuss the matter sensitively with them. They should be encouraged to accept the person’s wishes and it should be made clear that they do not have the legal right to veto or overrule those wishes.

176. In a situation in which the list is ranked and agreement cannot be reached between people of the same rank; it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.

177. Those close to the patient will be involved in making best interests decisions relating to people with incapacity where DCD is a possibility. As described in paragraph XXX, ODR consent is one factor to take into account in a best interests assessment for making ante-mortem interventions to facilitate organ donation in DCD cases.

178. In addition those close to the patient will be asked for information which will help to establish whether his or her organs are suitable for transplantation, for example by providing information about medical, social and travel history.

**Consent for organ donation – children**

179. The position for a child, who was competent to reach a decision before they died and consented to organ and tissue donation taking place after their death, is legally no different from that of an adult. The child’s consent is sufficient to make the removal, storage or use of their organs for transplantation lawful.
180. The Deemed Consent Act makes it clear that the consent for organ and tissue donation from a child cannot be deemed.

181. If a child did not make a decision, or was not competent to make a decision, the HT Act makes clear that in this instance the appropriate consent for organ and tissue donation will be that of a person with parental responsibility for the child immediately before he/she died. The consent of only one person with parental responsibility is necessary. Where no person had parental responsibility for the child immediately before they died, appropriate consent will be that of someone in a qualifying relationship to them.

182. Further information on consent by and on behalf of a child can be found in paragraphs XX to XX of Code A.
Part 2(b) - Deemed Consent (England)

Circumstances in which consent can be deemed

Insert:
- Circumstances in which consent can be deemed;
- Definition of excepted adult
- Guidance where no family/friends are contactable.

Establishing whether the potential donor is an excepted adult

What is meant by “in England”?

183. For the purposes of the Deemed Consent Act, “in England” means within a English local authority area. Information on the local authorities can be found on the local government structure and elections webpage.

184. In most cases the SNOD will be able to establish whether a person lived (and died) in England, either from medical records or through discussions with the family/friends.

185. If there is doubt, the SNOD should check whether the deceased person’s address was in England. If this is not possible, for example the service is unavailable for a period of time which would mean the opportunity for donation is missed, and the person cannot safely be assumed to be resident in England, then the express consent process should be followed.

Residency

186. In the majority of cases a SNOD will be able to establish where the deceased person lived, and whether they were ordinarily resident (see paragraphs XX to XX) at an address in England.

187. For deemed consent to apply, the deceased person must have lived in England for twelve calendar months prior to their death. For the purposes of deemed consent the time of death is taken to be the date on which death is confirmed.
by one of the processes laid out in the AoMRC Code of Practice for the Diagnosis and Confirmation of Death.

**Example**

An adult dies in a hospital on 15 February. It is established by speaking to their family/friends that they moved to England on 16 February of the previous year. Deemed consent does not apply to them, as they had not lived in England for twelve calendar months when they died.

Had the person’s friends/family confirmed that they had moved to England on 15 February, and that the person was ordinarily resident in England, deemed consent would apply to them, as they had lived in England for twelve calendar months when they died.

The twelve month period test does not involve counting the number of days a person had lived in England. Rather, it is necessary to establish that a person had lived in England for twelve calendar months.

188. In some cases, it may not be possible to establish the exact date a person started living in England. For example, their family/friends may not be able to remember exactly when they moved to England, but do know it was within the last ten to fourteen months.

189. When this is the case and there is no documentary evidence available to confirm the time spent at the address, then deemed consent should not apply and the express consent process should be followed.

190. If there is documentary evidence, but this cannot be accessed within a timeframe which would allow donation to go ahead, for example it is 8pm and the office where the information is held does not reopen until 9am the following day, then deemed consent should not apply and the express consent process should be followed.

**Ordinarily Resident**

191. The test for ordinarily resident attaches a number of qualities to a person’s residency, in order for them to be considered ordinarily resident. These qualities are:

a) The residence was adopted voluntarily.
The fact that the person chose to come to England at the request of an employer rather than seek another job does not necessarily make their presence in England involuntary. For example, the SNOD will need to ask questions to gather evidence in such circumstance and make a decision on whether the person’s residence had a voluntary quality to it.

b) The person was resident for settled purposes.

This might be for only a limited period, but has enough continuity to be properly described as settled. Business, employment and family can all provide a settled purpose, but this list is not exhaustive.

c) The person’s residency in England supported the regular order of their life for the time being.

The person may have had temporary absences from England and still be considered ordinarily resident. The SNOD will need ask questions to gather evidence in such circumstance and make a decision on whether the person’s residence supported the order of their life.

192. These qualities must be assessed on a case-by-case basis, and whether the qualities have been satisfied will primarily be a question of fact and degree. In many cases the SNOD will be able to establish easily whether the person’s residence was characterised by the qualities above. When it is not initially clear that this is the case, it is recommended that there is a discussion with family/friends to gain more information about how the person would have characterised their residency.

193. The ordinarily resident test involves weighing up information, and when a SNOD is in doubt about whether the person would have been ordinarily resident, the express consent process should be followed.

Example

A person may work in London and live there four nights a week, and spend the other three nights at their family home in Glasgow. The SNOD should ask questions of the family/friends to establish how the person would have identified their residency. The SNOD may wish to ask where the person would have referred to as home. It will then be for the SNOD to weigh up the evidence to establish whether or not the person was ordinarily resident in England.
194. The SNOD will need to consider whether the person’s residence in England was:

a. Voluntary; and  
b. For a settled purpose; and  
c. Supported the regular order of their life for the time being.

**Students**

195. Education can have the quality of a settled purpose and a student may be regarded as a person ordinarily resident in a particular place. It will be for discussion with the person’s family/friends to determine whether the student’s residence in England had the necessary qualities described above before deciding whether deemed consent applies.

**Prisoners**

196. A person who is in prison cannot be stated to be residing in England through choice, and cannot be considered ordinarily resident in England during their time in prison. This includes prisoners who normally live in England and who are in prison in England. People in prison cannot have their consent to organ donation deemed.

**Armed Forces**

197. People serving in the armed forces who are directed to live in England (i.e. who are posted to England) cannot be considered to be ordinarily resident in England because they will not be living in England voluntarily. They cannot therefore be deemed to have given consent to organ donation.

198. The families of armed forces personnel who have been posted to England who decide to join them for the duration of their posting may in certain circumstances, as established by case law, be considered to be ordinarily resident in England. Therefore, the SNOD will need to ask questions in order to establish whether such family members would have been considered ordinarily resident, on a case-by-case basis.

199. Those people serving in the armed forces, who are not directed to live in England, but do so out of choice, can have their consent to organ donation deemed to have been given, if they are neither a child nor an excepted adult.
**Other groups**

200. There are other groups of people, for example those detained under mental health legislation and diplomatic staff who may or may not reside in England voluntarily. It will be for the SNOD to ask questions of family/friends to establish whether the residence was voluntary, and this will need to be done on a case-by-case basis.

**Mental capacity**

201. Deemed consent does not apply to people who for a significant period before dying lacked the capacity to understand the notion that consent to transplantation activities can be deemed to be given.

202. If a person did lack capacity to understand that consent can be deemed for a significant period before their death, then the express consent process should be followed.

203. If at the point at which a person lost capacity deemed consent did not apply to them, for example, they were a child or did not live in England, then their consent cannot be deemed.

204. In some cases it will be evident that a person lacked capacity for a significant period before dying as they may, for example, have been in a coma for a significant period.

205. When it is not evident, but there is a possibility, in order to establish whether a person lacked capacity for a significant period before their death, the SNOD should take the following steps:

   d. Check the medical records of the person to establish whether there was any history of conditions or illness which may have impacted on the person’s capacity to understand the notion of consent being deemed or any assessment of the person’s capacity to understand the notion of consent being deemed. It is important to note that a record of an episode or episodes of such an illness would not necessarily mean that a person would not have been able to understand the notion. However, it should prompt further investigation by the SNOD.

   e. If there is no indication in the medical records of a condition or illness which may have impacted the person’s capacity to understand deemed consent or any assessment of the person’s capacity to understand the
notion of consent being deemed, then the SNOD should make a note of this.

206. If there is an indication in the medical records of a condition or illness that may have impacted on the person’s capacity to understand deemed consent, the SNOD should undertake further investigations which address the specific circumstances of the person’s condition or illness. The issue of mental capacity should be raised by the SNOD when speaking to the friends/family to inform them that consent will be deemed, in order to check that the person did have capacity. It is envisaged that this would take the form of a simple question, for example, “Do you think that your relative/friend would have understood that consent to organ donation could be deemed?”

Example

If the person had been in hospital for some time it may be appropriate to speak to a member of the team caring for them to establish their level of understanding of medical and consent issues generally.

207. Where there is evidence of an illness that may have impacted the person’s capacity to understand deemed consent, in most cases it will be the family/friends who are able to provide the SNOD with the most accurate information as to whether they understood consent to organ donation could be deemed. The SNOD should ask the family/friends whether they believe the person had a level of capacity to understand deemed consent, or analogous notions. This may be a detailed discussion, and if at the end of this the SNOD is not satisfied on the balance of probabilities (that is, that it is more likely than not), that the person could have understood the notion of deemed consent, then the express consent process should be followed.

208. A person may have made an advance statement in regard to organ donation prior to losing capacity or have nominated a person with Lasting Power of Attorney on health and welfare to make decisions in regard to organ donation. If this is the case, then the decision recorded in the advance statement or the decision communicated by the Lasting Power of Attorney is express consent or refusal.

**Significant period**

209. The Deemed Consent Act requires a person to have lacked capacity to understand the notion of deemed consent for a significant period before dying, to be a person excepted from deemed consent.
210. The exact duration that a person lacked capacity is not specified in Deemed Consent Act, but the period must be significant and this means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given. The significant period test is, therefore, an objective test in the sense that it must be based on the circumstances of each case and the facts presented. The significant period only negates deemed consent; if the person had made a decision to consent, or not to consent, then that express consent remains in force regardless of a subsequent loss of capacity.

211. In practice, a significant period should mean that the person did not have capacity to understand the notion of deemed consent for a period of at least twelve months before their death. The person’s family, friends or carers should consider the significant period to be a period which is long enough that the person’s decision not to register a decision in regard to organ donation could not be said to be a conscious decision.

212. The twelve month period is provided in this first Code of Practice on the Deemed Consent Act in order to provide regulatory certainty to SNODs and other practitioners.

213. If the potential donor is not an excepted adult then there consent can be deemed for the donation of any organs and tissues that are set out in Regulations. For all other organs and for tissue donation the consent options are set out in the section ‘Express consent (Northern Ireland and England (excepted adults, children and other excluded categories)’.

Role of the family – considerations for deemed consent

Insert:

- The role of the family in providing evidence to establish the wishes of the deceased
- Case study.

Faith and Cultural considerations

214. The ODR allows a person to state that their faith is important to their organ donation decision and that their family and anyone else appropriate should be
consulted about how organ donation can proceed in line with a donor’s faith or beliefs. This is to ensure that any faith and cultural considerations are observed.

215. This information is visible to the SNODs and transplant professionals. It is recommended that SNOD seeks to identify appropriate people and give them time and information to ensure that any religious and cultural aspects are taken into consideration.

Other considerations

Preservation of organs in cases of uncontrolled donation after circulatory death (DCD)

Note:
- Particular attention to amends to this section in light of deemed consent
- Consider where this is best placed within the Code.

216. As outlined earlier in this Code (see paragraph X), where donation is a possibility, the deceased’s wishes regarding organ and tissue donation should be established as soon as possible. There may be occasions when steps need to be taken to preserve the viability of an organ, while it is being established if a decision on consent has been, or will be, made.
217. Preservation of parts of a deceased person’s body for potential use for transplantation is dealt with under section 43 of the HT Act. The HT Act makes it lawful to take minimum steps to preserve part of a body for potential transplantation, including in those situations where it is still being established if a decision on consent has been, or will be, made.

218. In uncontrolled DCD, the coroner’s jurisdiction, common law powers and statutory obligations under coronial law also arise automatically and immediately and must also be taken into account when any decision regarding taking steps to preserve an organ is required. It should be borne in mind that the parallel powers of the coroner arise when the body is lying in that coroner’s jurisdiction as well as within a hospital, nursing home or other institution.

219. In all cases, steps should therefore be taken as soon as possible to find out not only the deceased’s wishes on donation, or where this is unknown, the views of the relatives of the deceased (see paragraphs 30-39 of Code A), but also whether the local coroner is obliged or otherwise intends to assume jurisdiction to investigate the cause of death. Further information can be found in Annex B.

220. However, as outlined above, it will not always be possible to obtain a decision on consent quickly enough to prevent the relevant organs deteriorating. In these circumstances, while continuing to establish a position on consent, it is lawful for the establishment to:

a) take the minimum steps necessary (subject to the coroner’s consent where required) to preserve the part for use in transplantation using the least invasive procedure, such as cold perfusion and intraperitoneal cooling;
b) retain the body of a deceased person for that purpose.

221. Whether a procedure constitutes the ‘minimum steps’ should be considered in terms of both what is least invasive to the donor, and also in terms of what may be perceived as appropriate by the relatives.

222. Permission to carry out preservation of this type ceases when it has been established that consent has not been given for organ removal. All procedures to preserve the body must then be stopped immediately.

223. The taking and storage of blood samples is a necessary action to ensure the preserved organ can be used for transplantation in cases where consent for donation is later given. Blood samples can also therefore be taken before perfusion in order to preserve the option for donation until a decision on consent has been established.
224. Guidance on the process for preservation is provided in the BTS Guidelines relating to transplantation from donors after circulatory death.

**Working with the coroner in cases requiring steps to be taken for organ preservation**

225. In order to ensure that conflicts do not arise between the provisions of section 43 of the HT Act for the preservation of organs and the lawful powers or authority of the coroner when a body is lying in the coroner’s jurisdiction, a generic memorandum of understanding should be pre-emptively agreed with the local coroner where possible. Specific notification of the coroner should also occur on a case-by-case basis where appropriate.

226. **Annex B** provides good practice guidelines on the detailed steps to be taken in the process of organ preservation and working with the coroner. There will need to be local agreement to, and ownership of, the guidelines by the coroner and the organ retrieval teams.
Annex A

Legislative background and context

1. The Human Tissue Authority (HTA) is the regulator for human organs, tissues and cells. The HTA was established by the Human Tissue Act 2004 (HT Act) in 2005, following the discovery of establishments removing and retaining human organs and tissue without consent. The HT Act addressed this issue and brought together other existing laws that related to human tissue and organs.

2. The HT Act applies to the removal, storage and use of human organs and tissue for scheduled purposes in England, Wales and Northern Ireland, with the exception of the provisions relating to the use of DNA, which also apply to Scotland.

3. Under section 14(3) of the HT Act, the HT Act and the guidance given in the Codes of Practice do not apply to bodies or relevant material where:

   a) the person died before the HT Act came into force on 1 September 2006; and
   b) at least 100 years have elapsed since the date of the person’s death.

4. The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 (the Regulations) lay down the responsibilities of the HTA in relation to the donation of transplantable material from living donors, including those who lack capacity to consent.

5. On XX a deemed consent system for organ and tissue donation after death will become operational in England, as a result of implementation of Organ Donation (Deemed Consent) Act 2019. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA’s regulation of living organ donation. These Codes of Practice apply to organ and tissue donation from the deceased in England and Northern Ireland.

6. The HTA is the Competent Authority in the UK for the implementation of the European Union Tissue and Cells Directive 2004/23/EC (EUTCD). The EUTCD sets standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

7. The requirements of the EUTCD are transposed into UK law via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUTCD. Establishments licensed

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6 Defined by the HT Act and explained in further detail in the glossary.
under the Q&S Regulations should refer to the HTA’s Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment.

8. The HTA is the Competent Authority in the UK for the implementation of the European Union Organ Donation Directive 2010/53/EU (EUODD), which sets quality and safety standards for organ donation and transplantation. The requirements set out by the EUODD have been transposed into UK law through The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the Q&S (Organs) Regulations) and The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014. With the exception of Code A: Guiding principles and the fundamental principle of consent, the Codes of Practice do not provide guidance on complying with the requirements of the EUODD. Establishments licensed under the Q&S (Organs) Regulations should refer to the HTA’s The Quality and Safety of Organs Intended for Transplantation: a documentary framework.

9. On 1 December 2015 a deemed consent system for organ and tissue donation after death became operational in Wales, as a result of the implementation of the Human Transplantation (Wales) Act 2013. This legislation relates to donation of organs and tissue from the deceased, and as such does not have an impact on the HTA’s regulation of living organ donation. These Codes of Practice do not apply to organ and tissue donation from the deceased in Wales; the HTA has published a Code of Practice on the Human Transplantation (Wales) Act 2013 for establishments in Wales who work under the deemed consent for deceased organ donation system.

Scotland

10. The HTA’s remit does not extend to Scotland, and therefore the HTA’s Codes of Practice do not apply to establishments in Scotland.

11. A separate piece of legislation, the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), applies to Scotland. The HTA’s remit in Scotland is described in a letter titled Human Tissue (Scotland) Act 2006: A guide to its implications for NH Scotland, which the Scottish Health Department letter issued on 20 July 20067.

12. The HTA assesses applications for living organ donation and donation of bone marrow and PBSCs on behalf of Scottish Ministers who delegated this

responsibility to the HTA. The law in Scotland is significantly different from that in the rest of the UK, so this code does not apply in Scotland.
**Status and use of the Codes of Practice**

13. Throughout the Codes, the word ‘**must**’ applies to all legal requirements derived from primary and secondary legislation (for example, the legal requirement to hold a licence to store human tissue for use for a scheduled purpose, the conditions of any licence and the requirements set out in any directions issued by the HTA). It also applies to the duty to abide by the HTA’s licensing Standards. We use the word ‘**should**’ when providing advice on how to meet these requirements.

14. Establishments are expected to follow the guidance contained in the Codes. Observance of the guidance is one of the ways in which the HTA assesses that establishments are complying with legal requirements. Failure to follow a Code of Practice is not in itself a criminal offence under the HT Act, but the HTA will consider carefully any breach of a Code of Practice when considering whether there are grounds to take regulatory action.

**Other advice and guidance**

15. The Codes of Practice complement each other and should be read alongside other relevant advice and guidance, which is either referenced in the text or provided on the HTA’s website. The Codes of Practice may also refer to guidance which has been produced by a number of other organisations. The HTA is not responsible for the content of others’ guidance, but does recommend that practitioners follow this guidance when they fall within its remit. Guidance that has been produced in collaboration with the HTA will appear on our website.

16. The HTA’s Codes of Practice and other HTA guidance should, however, be used as the definitive source of information for issues within our remit. If you are in any doubt, please contact the HTA or seek your own legal advice. Regulated sectors should also keep up to date with other relevant legislation.
Annex B

Guidelines for transplant teams and coroners in cases of potential uncontrolled DCD requiring steps to be taken for organ preservation

The following steps in the process are recommended:

1. The potential donor should be identified by emergency department staff. The coroner must be informed and advised whether a medical practitioner will issue a Medical Certificate of The Cause of Death (MCCD) or that the death is sudden and of unknown cause or unnatural, traumatic or violent.

2. The SN-OD should be contacted to attend, in order to determine likely suitability based on history and duration of warm ischaemia, and liaise with the coroner’s officer or court staff.

3. Any requirements of the coroner should be met to enable determination of the cause of death. This may mean that the coroner requires a post-mortem examination and that perfusion and organ retrieval cannot proceed. If the coroner exercises discretion in favour of permitting perfusion subject to further investigations, then the local memorandum of understanding agreed with the coroner should be adopted, in order to obtain blood samples for potential toxicology as well as samples required for potential organ retrieval and donation.

4. Certain criteria may mean that this could proceed without immediate coroner notification in some situations. It is possible that when death is verified in the emergency department and then certified by a registered medical practitioner who is able to issue a MCCD for a natural cause of death, then the death does not need to be reported to the coroner. If in doubt then the case should be reported.

5. The ODR should be checked in order to ascertain the wishes of the patient with respect to organ donation.

6. If the patient is registered on the ODR, this should be communicated to the nominated representative or person in a qualifying relationship if they are available and, subject to coroner approval, perfusion should commence. In the case of a child, the person with parental responsibility must be consulted in the first instance.

7. If the patient is not registered on the ODR and their wishes relating to donation are not known, consent should be sought from the nominated representative or
person/s in a qualifying relationship and, subject to the coroner’s approval, perfusion should commence.

8. If the wishes of the deceased are unknown and no nominated representative or person/s in a qualifying relationship can be contacted, perfusion may be instigated, subject to the coroner’s approval, while attempts to contact the nominated representative or person in a qualifying relationship continue.

9. Subject to the coroner’s approval as discussed above, and the consent of the nominated representative or person in a qualifying relationship, the femoral vessels should be cannulated. Blood specimens for both the coroner and organ donation purposes must be taken before perfusion is started.

10. Where the deceased’s wishes are unknown and the nominated representative or a person/s in a qualifying relationship is not available before perfusion being instigated, consent, or refusal to consent, to organ donation should be confirmed/obtained as soon a person in such a relationship is available. In any event, it should be advised that the death may still remain subject to the jurisdiction of an investigation by the coroner.

11. If consent for organ and / or tissue donation has been established or obtained, the patient may be transferred to theatre for removal of organs.

12. All conversations and discussions including operative findings should be documented in the patient’s notes for reference by other healthcare professionals and the coroner.
## Glossary

<table>
<thead>
<tr>
<th>Term</th>
<th>HTA definition</th>
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<tbody>
<tr>
<td>Advance Decision</td>
<td>An advance decision is a decision made by a living person, when they had capacity, to refuse a specific type of treatment at some time in the future. To be legally binding in England and Wales, an advance decision must comply with a number of criteria which are described in the Mental Capacity Act 2005. With regard to organ and tissue donation, an advance decision could be used to exclude the possibility of donation from a living adult who lacks capacity at the time of the proposed donation.</td>
</tr>
<tr>
<td>Anatomical</td>
<td>Examination by dissection for the purpose of teaching, studying or conducting research into the structure of the human body.</td>
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<td>examination</td>
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<tr>
<td>Ante-mortem</td>
<td>Clinical investigations or interventions that take place preceding death.</td>
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<tr>
<td>Appropriate</td>
<td>Defined in the HT Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.</td>
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<tr>
<td>consent</td>
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<td>Best interests</td>
<td>A test of a person’s best interests takes into account not only the medical aspects, but also the wider emotional, psychological and social aspects of the potential medical procedure, as well as the risks.</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>A spongy tissue found in the hollow centres of some bones. It contains specialist stem cells, which produce the body's blood cells.</td>
</tr>
<tr>
<td>Cells</td>
<td>Individual human cells or a collection of human cells that are not bound by any form of connective tissue.</td>
</tr>
<tr>
<td>Coercion/</td>
<td>The HTA examines whether the recipient and donor have been put under any coercion or duress when assessing Independent Assessor reports. Both coercion and duress are referred to in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but they are not distinguishable in law. The HTA interprets coercion or duress to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.</td>
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<td>Duress</td>
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<tr>
<th>Term</th>
<th>HTA definition</th>
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<tr>
<td>Coroner</td>
<td>Coroners are independent judicial office holders, appointed by a local council. They investigate deaths that have been reported to them if it appears that the death was violent or unnatural, the cause of death is unknown or the person died in prison, police custody, or another type of state detention. In these cases coroners must investigate to find out, for the benefit of bereaved people and for official records, who has died and how, when, and where they died. As part of their duties, coroners authorise post-mortem examinations and conduct inquests.</td>
</tr>
<tr>
<td>Court of Protection</td>
<td>Makes decisions on financial or welfare matters for people in England and Wales who are unable to make decisions at the time they need to be made because they lack mental capacity to do so.</td>
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<tr>
<td>Deemed consent</td>
<td></td>
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<tr>
<td>Diagnosis</td>
<td>The identification of the nature of an illness or other problem.</td>
</tr>
<tr>
<td>Directed donation</td>
<td>A form of donation where a person, usually a living person, donates an organ or part organ to a specific, identified recipient with whom they have a genetic or pre-existing emotional relationship.</td>
</tr>
<tr>
<td>Directed altruistic donation</td>
<td>The HTA defines these as cases which fulfil two conditions (a) the donation is being directed to a specified individual and (b) there is no evidence of a qualifying genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party - either a person or other mechanism such as a social networking site - bringing the donor and recipient together for the purpose of transplantation.</td>
</tr>
<tr>
<td>DNA</td>
<td>DNA stands for deoxyribonucleic acid. DNA is found in the nucleus of all cells, and contains the genetic information for the development and working of living organisms including human beings. The study of DNA is used in forensics, gene therapy, relationship (including paternity) testing and bioinformatics. Find out more information about the HTA’s role with regards to DNA on the HTA’s website.</td>
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<td>Term</td>
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<tr>
<td>Domino donation</td>
<td>A form of living donation in which an organ is removed for the primary purpose of the person’s medical treatment. The organ removed may prove suitable for transplant into another person. The HTA does not regulate domino donations.</td>
</tr>
<tr>
<td>Donated material</td>
<td>For the purposes of the HT Act, the term ‘donated material’ refers to the body of a deceased person, or relevant material which has come from a human body, which is being stored or used for scheduled purposes with appropriate consent.</td>
</tr>
<tr>
<td>Donation</td>
<td>The act of giving human tissue, cells, organs or part organs for a scheduled purpose, either during life or after death.</td>
</tr>
<tr>
<td>Donation after Brainstem Death (DBD)</td>
<td>A form of organ donation in circumstances where a patient, whose death has been diagnosed using neurological criteria, continues to be ventilated. This keeps the heart beating and blood circulating after death, until after donation takes place.</td>
</tr>
<tr>
<td>Donation after circulatory death (DCD)</td>
<td>A form of organ donation in circumstances where the deceased donor was not ventilated at the time of death. Donation therefore occurs after death is diagnosed and confirmed using cardio-respiratory criteria. This is described as controlled when treatment has been actively withdrawn within a hospital setting or uncontrolled where a patient has experienced an unexpected cardiac arrest from which they cannot be resuscitated.</td>
</tr>
<tr>
<td>Donor</td>
<td>Every human source, whether living or deceased, of tissue, cells, organs or part organs.</td>
</tr>
<tr>
<td>Duress (Coercion)</td>
<td>Both words are referred to in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, but are not distinguishable in law. The HTA interprets duress to mean that the will of the person required to act has been overborne such that they can no longer make an independent decision.</td>
</tr>
<tr>
<td>Health and Social Care (HSC) Trust</td>
<td>Health and Social Care (HSC) Trusts provide integrated health and social care services across Northern Ireland. For further information see the Department of Health, Social Services and Public Safety’s (DHSSPS) website.</td>
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<td>Term</td>
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<tr>
<td>Human application</td>
<td>In relation to tissue or cells, human application means use on or in a human recipient, including use in applications situated or occurring outside the body, but not including use when tissue and cells are removed from and applied in the same person within the same surgical procedure.</td>
</tr>
<tr>
<td>Independent Assessor</td>
<td>The designation given by the HTA to the “qualified person” for the purpose of The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. Independent Assessors are trained by the HTA and undertake the statutory interviews with the donor and the recipient in each application for living organ donation.</td>
</tr>
<tr>
<td>Intraperitoneal cooling</td>
<td>A method of surface-cooling organs by infusing cold fluid into the abdominal cavity to aid preservation of the donor after death for the purpose of transplantation.</td>
</tr>
<tr>
<td>Lasting Power of Attorney (LPA)</td>
<td>A Lasting Power of Attorney (LPA) is a power of attorney under which the donor (a person aged 18 or over) confers authority to another person or people (a third party) to make certain decisions on their behalf, should they lose capacity in the future. An LPA is a legal document and decisions that the third party makes are as valid as any made by the donor. An attorney is bound by the principles set out in the Mental Capacity Act; for example, any decisions they make must be made in the best interests of the person lacking capacity. Further information about LPAs is set out at chapter 9 of Part One of the Mental Capacity Act. An LPA is only applicable in England and Wales.</td>
</tr>
<tr>
<td>Licensed premises</td>
<td>Where the licensed activity takes place.</td>
</tr>
<tr>
<td>Licensing</td>
<td>A number of activities can only be carried out when an establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under a HTA licence. All establishments working under a HTA licence must work to specified Standards set by the HTA.</td>
</tr>
<tr>
<td>Minimum steps</td>
<td>The HT Act allows for the minimum steps necessary to be taken to preserve organs in a state which allows successful donation, using the least invasive procedure such as cold perfusion and intraperitoneal cooling.</td>
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<tr>
<td>Term</td>
<td>HTA definition</td>
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<tr>
<td>Nominated representative</td>
<td>A person appointed by a person to represent them after their death for the purposes of activities under the HT Act for which consent is required. A nominated representative may be entitled to consent to the removal, storage and use of the body or tissue for any of the scheduled purposes, other than anatomical examination or public display.</td>
</tr>
<tr>
<td>Non-directed altruistic donation</td>
<td>A form of donation where a healthy living person donates an organ or part organ to an unknown recipient, that is, someone they have never met and is not genetically related or known to them.</td>
</tr>
<tr>
<td>Non-directed altruistic donor chains</td>
<td>A form of donation where a non-directed altruistic donor donates their organ into the paired/pooled scheme. By matching two or more recipients, a chain of operations can be carried out. The remaining organ at the end of the chain is then donated to the best matched recipient on the national waiting list.</td>
</tr>
<tr>
<td>Organ</td>
<td>Defined by the Human Tissue Act (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, as amended, as a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with a significant level of autonomy. Part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirement of structure and vascularisation.</td>
</tr>
<tr>
<td>Organ Donor Register (ODR)</td>
<td>A confidential, computerised national database managed by NHS Blood and Transplant (NHSBT), which holds details of people who have signed up to become organ donors in the event of their death. It also holds details of people who have stated they do not want to donate their organs after their death. The register is used after a person has died to help establish whether they wanted to donate and if so, which organs.</td>
</tr>
<tr>
<td>Paired and pooled donation</td>
<td>A form of donation where a healthy living person is unable to (or chooses not to) donate because they are either incompatible with their intended recipient, or prefer a better match. They may be matched with another donor and recipient in the same situation in the National Living Donor Kidney Sharing Schemes. The donor organs are then swapped. When two pairs are involved it is a paired donation and where more than two pairs are involved it is a pooled donation.</td>
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<tr>
<td>Term</td>
<td>HTA definition</td>
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<tr>
<td>Parental responsibility</td>
<td>A person who has parental responsibility will usually, but not always, be the child’s parent. The category of persons with parental responsibility is as set out in the Children Act 1989.</td>
</tr>
<tr>
<td>Payment or reward (in IA and AA cases)</td>
<td>The HTA examines whether payment or reward has been given, offered or received when assessing Independent Assessor cases. Under the Human Tissue Act, a person is committing an offence if they:</td>
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<tr>
<td></td>
<td>a) give, offer or receive any type of reward for the supply or offer of supply of any transplantable material;</td>
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<td>b) look for a person willing to supply any transplantable material for reward;</td>
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<tr>
<td></td>
<td>c) offer to supply any transplantable material for reward;</td>
</tr>
<tr>
<td></td>
<td>d) initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any transplantable material;</td>
</tr>
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<td></td>
<td>e) take part in the management or control of any type of group whose activities consist of or include the initiation or negotiation of such arrangements;</td>
</tr>
<tr>
<td></td>
<td>f) cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any transplantable material for reward, or indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising, including via social media.</td>
</tr>
<tr>
<td>Perfusion</td>
<td>A method of treating organs to preserve them before transplantation. In the deceased donor this will take place after death.</td>
</tr>
<tr>
<td>Peripheral blood stem cells (PBSCs)</td>
<td>Peripheral blood stem cells are the source of all blood cells. They are found in the bloodstream and are formed in bone marrow. They receive signals that direct them to differentiate into all the cell types found in blood (red cells, white cells or platelets). They can be mobilised from the bone marrow into the bloodstream by giving a drug, and collected with an apheresis machine.</td>
</tr>
<tr>
<td>Post-mortem examination</td>
<td>Dissection and examination of a body after death, principally in order to determine the cause of death or the presence of disease processes.</td>
</tr>
<tr>
<td>Practitioner</td>
<td>A person working with relevant material in an establishment licensed by the HTA.</td>
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<tr>
<td>Term</td>
<td>HTA definition</td>
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<tr>
<td>Procurement</td>
<td>The processes by which tissues and cells are made available, including the physical act of removing tissue and the donor selection and evaluation.</td>
</tr>
<tr>
<td>Qualifying relationship</td>
<td>The relationship to the deceased of a person/s who can give consent for the removal, storage and use of tissue from the deceased person's body for scheduled purposes, if the deceased person did not indicate their wishes in life or appoint a nominated representative.</td>
</tr>
<tr>
<td>Relatives</td>
<td>Throughout the Codes, the term ‘relatives’ should be taken to include a spouse or partner and, in cases where there are no relatives, close friends of the deceased person. Decisions regarding consent should be made according to the hierarchy of qualifying relationships as set out in the HT Act.</td>
</tr>
<tr>
<td>Relevant material</td>
<td>Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA’s website.</td>
</tr>
<tr>
<td>Research</td>
<td>A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications or new knowledge.</td>
</tr>
<tr>
<td>Term</td>
<td>HTA definition</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Scheduled purpose</td>
<td>Under the Human Tissue Act, consent must be obtained to remove, store or use bodies or relevant material for scheduled purposes. The licensing requirements of the HT Act also relate to activities for scheduled purposes. Scheduled purposes are divided into those which apply generally, and those which apply to the deceased only.</td>
</tr>
<tr>
<td></td>
<td>• Part 1: Purposes requiring consent: General – anatomical examination; determining the cause of death; establishing after a person’s death the efficacy of any drug or other treatment administered to him; obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); public display; research in connection with disorders; or the functioning; of the human body, transplantation.</td>
</tr>
<tr>
<td></td>
<td>• Part 2: Purposes requiring consent: Deceased persons – clinical audit, education or training relating to human health, performance assessment, public health monitoring, and quality assurance.</td>
</tr>
<tr>
<td>Specialist Nurse for Organ Donation (SN-OD)</td>
<td>A senior nurse who is the focal point of contact for organ donation within the Hospital / Trust. The role encompasses different aspects which all come together in the identification and referral of potential organ and tissue donors.</td>
</tr>
<tr>
<td>Specialist Requester</td>
<td>Definition to be added.</td>
</tr>
<tr>
<td>Tissue</td>
<td>Any and all constituent part/s of the human body formed by cells.</td>
</tr>
<tr>
<td>Transplant Unit</td>
<td>A department within a hospital that provides range of transplant services to patients.</td>
</tr>
<tr>
<td>Transplantation</td>
<td>An implant of an organ or part organ, tissue or cells either from and into the same body or from one person to another.</td>
</tr>
<tr>
<td>Valid consent</td>
<td>Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question. Valid consent is explained in detail in Code A: Guiding principles and the fundamental principle of consent.</td>
</tr>
<tr>
<td>Term</td>
<td>HTA definition</td>
</tr>
<tr>
<td>-----------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Vascularised Composite Allograft transplant</td>
<td>The transplantation of parts of the human body that contains multiple structures that may include skin, bone, muscles, blood vessels, nerves and connective tissue, that is recovered from the human donor as an anatomical or structural unit and requires its own blood supply and without altering its relevant characteristics. This may include novel transplants such as face, hand and limb and uterus.</td>
</tr>
<tr>
<td>Welfare deputy</td>
<td>A person who has been appointed and given the power to make certain decisions by the Court of Protection (see section 16(2)(b) of the Mental Capacity Act). Welfare deputies are only appointed in England and Wales.</td>
</tr>
<tr>
<td>Work-up process (in organ, bone marrow and PBSC donation cases)</td>
<td>A full medical assessment process involving a series of medical tests and investigations to determine whether a person is suitable as a living donor.</td>
</tr>
</tbody>
</table>
Year-two update of the HTA Strategy

Purpose of paper

1. This paper provides the Authority with drafts of the year-two update of the HTA Strategy document and KPIs (Annex A), the Digital, Data and Technology Strategy (Annex B) and the updated People Strategy (Annex C) for approval.

Decision-making to date

2. The draft strategy documents were approved by the CEO on 31 January 2019 for submission to the Authority.

Action required

3. Members are asked to:
   a. approve the year-two update of the HTA Strategy and KPIs (Annex A) for publication in April;
   b. approve the Digital, Data and Technology Strategy (Annex B), and
   c. provide comment and approve the revised People Strategy (Annex C).

Background

4. The Authority is responsible for setting the strategic direction for the HTA. 2019/20 is the second year of the HTA’s three-year strategic period (2018-2021).

5. At its away-day in September 2018, the Authority undertook a review of its operating environment and the balance of delivery and development activities. The Authority
also reviewed the draft Digital, Data and Technology Strategy and discussed development of the HTA’s People Strategy as the first stage in preparing for organisational transformation.

6. Following the away day and further SMT discussions, the executive has revised the HTA’s People Strategy to address the capability and transformation issues we face over the coming years.

**Next steps**

7. As outlined in the CEO’s report (HTA 02/19), the SMT continue to work on more detailed plans for the transformation programme, subject to formal approval of the business case by DHSC.

8. Preparations for the programme will be examined in more detail by ARAC at its meeting in February.
Introduction from the Chair

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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 overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

We also have a role in maintaining professional confidence; by assuring that human material being used by professionals has been obtained with the proper consent and is managed with appropriate care.

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 Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended);
- We license organisations involved in organ donation and transplantation as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended);
- 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 assess living organ donations to ensure donors are protected from duress or coercion, and that no reward is offered or 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.

In addition to our statutory role we are increasingly called upon to provide advice on areas related to, but not specified in, our legislation. This is particularly important in areas of emerging technology and cutting-edge research not originally envisaged when the Human Tissue Act was enacted.

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 donations 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 855 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 the individuals and organisations that undertake activities within the HTA’s remit acting within the standards and requirements of the legislation.

Guiding principles

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

Our values as an organisation in carrying out our role, expressed in all external interactions:

• 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 and collaborative, and involve and communicate effectively.

Key activities

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 2017 the HTA undertook a fundamental evaluation of the extent to which our 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 focused on evaluating our future operating environment and whether our resources are optimally aligned to where the risks are greatest.

An assessment of the evidence provided 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 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 unforeseen when the legislation was framed, and we need to be realistic about the limited opportunity for legislative change.

As one of the regulators operating in the field of life sciences, we are clear that effective, right-touch regulation can make a positive contribution to patient outcomes and economic growth. We are determined to play our role in the ambitious plans set out by the Government through the Industrial Strategy. In this last year we have also contributed to the debate on proposed legislative changes to consent provisions for organ donation in England, and have been fully engaged in preparations for the UK’s exit from the European Union.

We recognise that our staff are our key asset – their skill and dedication lie 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.

Our strategy therefore continues to focus on the steps we need to take over the next three years in order to operate 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. To achieve this we have further refined and shaped our plans for organisational transformation:

**Sustainability**

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.
Resilience

By resilience, we mean adapting our operating model to retain staff for longer and developing strategic alliances with other organisations to put us in a better position to manage unexpected demands.

Agility

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.

When we launched our new strategy last year we acknowledged that 2018/19 was a transition between the previous 3 year strategy and the new priorities. During the last year we have laid the foundations for changing the way we work. In 2019/20 our business plan will focus on the initial phase of our transformation programme, and delivering this alongside our core regulatory activity.

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 managing our fee levels based on work load and regulatory effort, including longer term planning to ensure continued financial viability.

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 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 nor 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. 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** - 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

**Delivery**

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 areas that involve an inherently greater risk to patient safety and public confidence 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, as amended)
- Organ Donation and Transplantation (under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, as amended)

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 welcome the significant degree of trust that the vast majority of 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 reporting, along with issues and complaints about licensed establishments that are raised with us by third parties, allows us to take action if
required. We also use the insight gained from investigations to share learning with those we regulate.

**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 Codes of Practice and 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 whom 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

We also engage virtually via our public panel and licensed establishment engagement panel, which provide fora for wider participation and further opportunities for those interested or affected by our work to be involved in, and inform, it.

**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.
Delivery objectives

- Deliver a right touch programme of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety;
- Deliver effective regulation of living donation;
- Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;
- Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards;
- Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us;
- 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 programme of site visits which provide assurance that standards are being maintained;
- 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 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 through organisational transformation alongside 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 continue to 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 the UK living kidney sharing scheme, placing pressure on staff resource. Although we have made good progress in increasing the numbers of our Independent Assessors, the sustainability of the Independent Assessor framework remains a significant strategic issue, and we will implement further measures to bolster this during 2019/20.

Improving compliance

Although in general we see a high level of compliance in our establishments, we are continuing to see an increase in the number of shortfalls against our standards on inspection. We will use the data and information we hold, and our close links with key stakeholders, to implement a targeted approach 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, and have implemented measures to more routinely review and utilise our core data. We recognise that we can further improve the quality and make better use of automation and technology to manage the data and information we hold, in order to ensure we identify trends and 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 the use of 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 those we regulate as and when it is needed.

**Development objectives**

Our development objectives are:

- Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
- 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, making it clear how to comply with new and existing regulatory requirements;
- Begin work on implementing a future operating model, which builds our agility, resilience and sustainability as an organisation.

**In the period covered by this strategy, we will:**

- Continue to implement the recommendations from our evaluation of risk across the human application sector and amend our approach as necessary;
- Further implement measures to improve the sustainability of the Independent Assessor framework;
- Continue to work with central Government and our licensed establishments to support 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;
- Further plan, develop and implement an organisational transformation programme.

**Deployment**

**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 has undergone a fundamental review.

We will develop proposals for widening the pool for recruitment outside London and the South East, and continue to build on the work we have done to 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 financial 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 and we have undertaken work with the Department to identify suitable future accommodation. We would expect these proposals to solidify early in 2019/20.

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 more 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 primarily through licence fees and Grant-in-Aid from the Department of Health and Social Care, with a small amount of income from other sources, e.g. from devolved administrations. 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 delivering value for money. 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. To inform this we will undertake a more fundamental review of our fee model in 2019/20.

In 2019/20 we were successful in securing approval for our business case to fund our organisational transformation. This will be funded via accessing existing reserves and will not necessitate an additional increase in licence fees or Grant-in-Aid. Robust oversight and governance of the transformation programme will ensure that these funds are used prudently to achieve tangible benefits for our stakeholders.
Deployment objectives

Our Deployment objectives are:

- Manage and develop our people in line with the HTA’s People Strategy
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- Provide a suitable working environment and effective business technology, with due regard for data protection and information security
- 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 to address key issues of concern;
- Build on the remodelling of our training and induction programme;
- Identify and strengthen the capabilities we will need to achieve success over this strategic period.
- Develop more formal arrangements for greater use of remote working to support our recruitment strategy;
- Give greater priority to information management and risk, ensuring that we comply with our requirements under relevant Data Protection legislation;
- 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;
- Plan for an office move by xxxx

Accountability

The Authority is made up of a Chair and eleven Members:

- Nine are appointed by the Secretary of State for Health and Social Care;
- One is appointed by the Welsh Cabinet Secretary for Health and Social Services; 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.
Authority members also fulfil a valuable role in contributing to project work and the HTA’s advisory groups, as well as providing counsel on a range of emerging issues. While the Executive implements this strategy by way of business plans, there are a number of mechanisms in place by which the Authority steers, scrutinises and reviews performance.

The Authority holds four board meetings per year, one of which is in public and an annual strategy away day. 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.
### Key Performance Indicators (KPIs)

<table>
<thead>
<tr>
<th>Strand</th>
<th>Objective</th>
<th>Type</th>
<th>Indicator</th>
<th>Activity</th>
<th>Performance Indicator</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery</td>
<td>Deliver a right touch programme of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety.</td>
<td>KPI</td>
<td>KPI:1</td>
<td>Undertake a risk based inspection / audit programme</td>
<td>180 site visits to take place during the business year across all sectors (year-to-date)</td>
<td>** this figure may have to be adjusted to account for development priorities</td>
</tr>
<tr>
<td>Delivery</td>
<td>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.</td>
<td>KPI</td>
<td>KPI:2</td>
<td>Take appropriate action for all regulatory non-compliances</td>
<td>100% of Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented (reported monthly)</td>
<td>This indicator is reported as a % for management information</td>
</tr>
<tr>
<td>Delivery</td>
<td>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.</td>
<td>KPI</td>
<td>KPI:3</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 standard operating procedure, and within five working days (average reported monthly)</td>
<td></td>
</tr>
<tr>
<td>Delivery</td>
<td>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.</td>
<td>KPI</td>
<td>KPI:4</td>
<td>Make appropriately evidenced decisions within agreed timeframes</td>
<td>100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days (average reported monthly)</td>
<td></td>
</tr>
<tr>
<td>Delivery</td>
<td>Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;</td>
<td>KPI</td>
<td>KPI:5</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 (reported monthly)</td>
<td></td>
</tr>
<tr>
<td>Delivery</td>
<td>Deliver a right touch programme of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety</td>
<td>KPI</td>
<td>KPI:6</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<td></td>
<td></td>
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</tr>
<tr>
<td></td>
<td>Make better use of our data to target our resources effectively</td>
<td></td>
<td>Report provided to the Authority annually (Q2) on the outcomes of our regulatory interventions and the impact on patient safety and public confidence</td>
<td>Remove as KPI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development</td>
<td>Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements</td>
<td>KPI</td>
<td>KPI:7</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>PROJECT: Deliver a project to implement EU Directives on Coding and Import / Export</td>
<td></td>
<td>Project red-amber-green (RAG) status remains amber or green during the course of the project (reported monthly) Embedding of requirements (Q1 onwards)</td>
<td>Remove</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Development</td>
<td>Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements</td>
<td>KPI</td>
<td>KPI:8</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| | PROGRAMME: Deliver a licensed establishment relationships programme as per plan specification | | To deliver the programme as agreed by HTA Management Group Elements of programme RAG status remain amber or green (reported monthly) Alpha testing of online community (Q1) Evaluation of options for DI training (Q2) | Remove as KPI, individual projects will be monitored as development activities and reported in development report.  
  - DI training  
  - Annual conference  
  - Sector events |
<p>| Development | Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk | KPI | KPI:6 |
| | PROJECT: Assessment of Risk in the Human Application sector and update of processes to reflect this | | Project RAG status remains amber or green during the course of the project (reported monthly) TPAs PPDs | Need indicative milestones and quarters |</p>
<table>
<thead>
<tr>
<th>Development</th>
<th>Further plan, develop and implement an organisational transformation programme</th>
<th>KPI</th>
<th>KPI:7</th>
<th>PROGRAMME: Develop and implement a series of business cases for projects which will form the HTA’s organisational transformation programme</th>
<th>Inspections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development</td>
<td>Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements</td>
<td>KPI</td>
<td>KPI:8</td>
<td>PROJECT: Develop a revised Code of Practice to provide practical guidance on the implementation of deemed consent for organ donation.</td>
<td></td>
</tr>
<tr>
<td>Deployment</td>
<td>Manage and develop our people in line with the HTA’s People Strategy</td>
<td>KPI</td>
<td>KPI:9</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%) (reported quarterly)</td>
</tr>
<tr>
<td>Deployment</td>
<td>Manage and develop our people in line with the HTA’s People Strategy</td>
<td>KPI</td>
<td>KPI:11</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 80%) (reported quarterly)</td>
</tr>
</tbody>
</table>

**KPI:7**
- Individual project RAG status remains amber or green during the course of the project.

**KPI:8**
- Project RAG status remains amber or green during the course of the project (reported monthly).
- Completion of drafting (Q1)
- Stakeholder consultation (Q2)
- Parliamentary approval (Q3)

**KPI:9**
- Reported as a % rather than RAG rating.

**KPI:11**
- Consideration of Senior Inspector role (Q1)
- Remove Update can be given in deployment report if required.
<table>
<thead>
<tr>
<th>Deployment</th>
<th>Manage and develop our people in line with the People Strategy.</th>
<th>KPI</th>
<th>KPI:10</th>
<th>Lead and advise on best recruitment procedures to maintain organisational capacity and capability</th>
<th>Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment</td>
<td>Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money.</td>
<td>KPI</td>
<td>KPI:11</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)</td>
</tr>
<tr>
<td>Deployment</td>
<td>Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money.</td>
<td>KPI</td>
<td>KPI:12</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>Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health Grant-in-Aid and devolved governments income) (reported quarterly)</td>
</tr>
</tbody>
</table>
HTA Digital, Data and Technology Strategy 2018 - 2021

Vision

Within three years, we will have developed capability, built stable and sustainable platforms, and enabled collaboration with our colleagues to deliver exceptional services for all of our stakeholders.

Executive Summary

This strategy has been developed as a guide for how the Human Tissue Authority (HTA) intends to transform and modernise its Digital, Data and Technology (DDaT) services to deliver positive outcomes for its staff, stakeholders and the public.

Successfully achieving the outcomes of this strategy will contribute significantly towards achieving the HTA’s strategic development and deployment objectives and enable others to achieve the delivery objectives.

Background

DDaT services are a key enabler for supporting the HTA’s strategic aim of assuring our status as a resilient and agile expert regulator.

The rate of change in the DDaT sectors is rapid and growth in the uptake of technologies such as cloud services, mobile devices, social media, high-speed broadband and open data create new opportunities for the HTA. In order to keep up with advances in technology and meet the increasing expectation of users of our services it is imperative that the HTA has a clear and progressive approach to continuously improving DDaT services at a sustainable pace.
Allied to the advances in technology comes a greater responsibility in relation to cyber security and information governance, which has an increasingly complex legal and compliance framework with which we must comply.

Although a relatively small organisation, the HTA needs to have in place the same controls and systems as those required by larger organisations albeit implemented on a smaller scale.

Outcomes

This section describes the outcomes that we aim to achieve with this strategy.

1. Remote working by design

Ambition

Our ambition is to support the HTA’s strategic aims of widening the pool for recruitment outside of London and the South East, and continuing to promote work/life balance and flexible working, through the strategic use of new technologies to enable much of the work we do to be carried out irrespective of location, thus contributing to building sustainability and resilience.

Background

Although the HTA is already reasonably well equipped to support remote working, this is not a situation that was consciously designed and is more the result of an evolution of working practices and technology solutions.

The balance of office workers to remote workers has recently tipped in favour of the latter and it is now that we must step back to review the solutions that we have on offer and actively consider if those offerings fully meet our requirements including how well they increase our sustainability and improve our resilience.

To achieve our ambition, we will

- Continue to use laptop and hybrid tablet devices rather than desktop computers to support greater mobility of work both within and away from the office
- Build fast, secure and reliable Wi-Fi networks in offices and support the safe use of Wi-Fi networks in many other public and private locations
- Continue to provide 4G smartphones using embedded and mobile Wi-Fi devices
- Make use of cloud storage and application hosting that allows access to data and applications from anywhere without having to download or return to an office to update
• Implement a centralised electronic document management and records system that reduces the reliance on email as a system of record and as a medium for transacting collaboration
• Support remote access technologies that allow employees to access the corporate network, including legacy applications, securely from home and on the move
• Improve VOIP (voice over internet) telephony to enable people to reliably use their computer and other devices as a telephone
• Enhance conferencing technologies – audio, video and web conferencing, mobile and static
• Enhance unified communications (UC) to integrate voice calling with messaging and conferencing technologies, and other enterprise systems
• Implement online collaboration and social networking technologies that let dispersed teams work together on “live” documents, chat to one another (e.g. instant messaging) and organise projects, tasks and timetables in a shared virtual space.

2. Improved processes

Ambition

We want to streamline our end-to-end processes, ensuring they meet the needs of the organisation today and remain adaptable to future changes, reduce waste, eliminate duplication and reduce costs.

Background

The HTA has a library of detailed process maps, built up over many years. Although we have carried out work to improve our processes this has not previously been carried out using industry recognised process improvement methodologies. A clear methodology will help tackle cultural resistance to change and improve accountability. An example of a Business Process Model and Notation (BPMN) process map can be seen at Annex A.

To achieve our ambition, we will

• Use Enterprise Architecture and Business Analysis techniques to define our processes
• Select and use the most appropriate process improvement methodologies to ensure our processes are streamlined, waste is eliminated and they contain no duplication
• Produce process diagrams using standardised Business Process Model and Notation (BPMN)
• Ensure that staff are well trained in new or revised processes
• Design systems which make it easy for staff to adhere to processes
• Include controls and audit mechanisms in the design of systems
3. Better use of information

Ambition

*Our ambition is to make better use of near real time information to inform risk assessment, regulatory decisions, business management and service improvement.*

Background

Information and data underpins the development of new policy, implementation of new or improved operational initiatives and delivery of our strategic priorities.

Knowing exactly where our information is and being assured of its quality not only supports our strategic thinking but also frees time for our colleagues to focus on what they do best.

We need to increase awareness of our information and data, build on our capabilities, tools and techniques to exploit the rich datasets we hold, and drive evidence-based, data driven decisions.

We must look for innovations in making our data available and accessible. Whether using data science techniques or business intelligence tools, an application programming interface (API) providing access to multiple datasets or logic processes, or an interactive map using geospatial information, we must not constrain our thinking.

To achieve our ambition, we will

- Promote a data-driven, intelligence led, and evidence based organisation
- Establish consistent policies, standards, processes and tools to enable a single, effective knowledge and information management system
- We will learn from recognised bodies such as the Data Management Association International (DAMA) and their Data Management Body of Knowledge (DMBOK) (see Annex B) and The National Archives (TNA) who set the standard for information and records management in government
- Develop data models and data dictionaries that clearly define our data holdings and where the data is held, ensure clear ownership and enable process owners to access and share information and data in line with common standards
- Develop mechanisms to access further data science capabilities, enabling greater data availability and accuracy
- Encourage the use of data analytics and predictive analytics, using tools such as Tableau or Microsoft Power BI, to anticipate events or policy changes
4. Better interfaces and digital content

Ambition

We want to design better interfaces and digital content for public and professional stakeholders, the public and staff.

Background

Over the past year, we have engaged more fully with the DHSC service design teams and learned more about Agile design and development and the government service standard. Although intended for national scale service design, the principles are the same for smaller scale developments and, by using those principles, we can ensure that we design and build the digital interfaces that people need and will use. We must also pay particular attention to the needs of users of our services who may have different accessibility requirements.

To achieve our ambition, we will

- Identify opportunities for digitisation
- Develop a design manual incorporating the HTA style, industry best practice and Government Digital Service guidelines
- Champion accessibility and inclusion, recognising the requirement for more flexible ways of working when designing services and solutions so no one is excluded from our digital, data and technology services

5. Improved information governance and assurance and cyber security arrangements

Ambition

Our ambition is to embed more deeply our information governance and assurance, and cyber security arrangements and to engender a Privacy by Design and Secure by Design culture.

Background

As a public body in the health and social care sector, we fall within the scope of a number of different information governance, cyber security and data protection frameworks and laws. We must be able to demonstrate that we comply with the requirements of those frameworks to the extent applicable for an organisation of our size and the law as it applies to the data that we process.

To achieve our ambition, we will
• Comply with applicable policies and standards to ensure that the confidentiality, integrity and availability of our information and data is protected
• Develop an internal Information Security standard, in a similar style as the licensing standards for HT Act sectors, that draws on all of the applicable policies and standards, presenting the requirements consistently and in a format that can be easily referenced
• Implement a training and awareness programme, using a mix of formal and informal approaches, to create a secure by default organisational culture

6. Partnerships

Ambition

*We want to work more closely with other organisations working in the health and social care sector and other regulators irrespective of their sector.*

Background

We have already benefited from a partnership with the Human Fertilisation and Embryology Authority (HFEA) through the sharing of the Director of Resources and Head of Finance roles and by working with them collaboratively on the GDPR project. We have not yet sought opportunities to collaborate with them on technical or digital initiatives.

We share a building with many other tenants, many of them operating in the same sector, and we must explore opportunities to partner with them where our interests align.

To achieve our ambition, we will

• Seek opportunities to extend our partnership with the HFEA, particularly on digital or technical initiatives
• Build relationships with the DDaT or equivalent functions of other tenants, sharing with them information about our DDaT strategic outcomes and, where there is alignment, explore opportunities for collaboration
• Engage more fully with regulatory and health and social care networks
7. Improved staff experience

Ambition

*We want to make sure that our staff have a good experience when working with any digital, data or technology solution whether they are in the office, working remotely or carrying out an inspection.*

Background

Our staff are our key asset and it is important that they have a good experience at work. We want them to have the right tools at their disposal to help them do their work efficiently and effectively wherever they are working and, seek their feedback on what does or does not work well for them.

To achieve our ambition, we will

- Engage staff in the design stages of DDaT solutions
- Regularly seek feedback from representative groups and all staff about DDaT solutions and the service that we provide to them on the whole

8. Increased capability of the IT organisation

Ambition

*Our ambition is to increase the capability of the Digital, Data and Technology function to ensure that we have the skills and capability to deliver improved services faster and cheaper.*

Background

The bulk of the DDaT function sits with Business Technology; one of the smallest teams in the HTA. All of the current skills and capability lie with one full time, permanent member of staff, supported by a number of suppliers each with their own areas of specialism. We need to be able to easily and consistently identify and develop or procure capability to fill skill gaps as we embark on this transformation programme.

To achieve our ambition, we will

- Adopt the SFIA framework version 3 to use as a common language for identifying and expressing the skills we need to succeed
• Develop a capability map showing all of the skills and capability that we might need to draw upon during this transformation period, and beyond. A draft capability map is at Annex C
• Work with the SMT and Head of HR on procurement and learning and development strategies to fill DDaT skills gaps across the organisation

9. Adoption of cloud services

Ambition

We want make better use of cloud storage and application hosting that allows access to data and applications from anywhere and reduces the reliance upon a single physical location.

Background

Cloud services have long been viewed with some scepticism resulting largely from a perceived lack of security and stability however, the industry has matured greatly in recent years. The largest cloud providers have invested heavily in their platforms and have made significant improvements in the aforementioned areas, to the extent that they are considered by many to be more secure than any single organisation could hope to make their own organisation. Another significant development in recent years is the opening of datacentres in the UK. This development removed the obstacle that many organisations faced, particularly those in the public sector, where they are required to store their data within the UK.

To achieve our ambition, we will

• Develop a cloud services target architecture that maps the maximum extent of cloud adoption desired by the HTA. A draft target architecture is at Annex D
• Develop cloud adoption transition maps synchronised with DDaT strategy implementation phases
• Provide full costs of cloud adoption for each phase and for the end state
• Provide assurance over cloud security to the Authority

10. Improved IT governance

Ambition

Our ambition is to have greater control over changes made within the Digital, Data and Technology scope, and to provide assurance and insight over those activities to the executive.

Background
As we place greater focus on, and reliance upon, DDaT solutions we must ensure that we have firm control over the management of changes to them. At present, we focus our change control efforts on new projects with little control over what are presumed to be minor changes. By improving our change control processes, we will gain a greater understanding of the likely impact of a change on other parts of the system and ensure that we focus our financial and staff resources on the changes likely to bring the greatest benefit.

**To achieve our ambition, we will**

- Change, or introduce new, processes designed according to best practices for delivering IT services. We will draw heavily from the IT Infrastructure Library as one of the most widely recognised IT Service Management frameworks
- Learn from COBIT 5 and the ISO 20000 family of standards to develop a set of standards and controls for the management and governance of IT.

**11. Continuous Improvement**

**Ambition**

*Our ambition is to instil a culture of collaboration with all of our stakeholders, continuously seeking open and constructive feedback on our performance and exploring opportunities to innovate and improve the services that we deliver. We want to empower our staff to give voice to and effect change where they see opportunities to improve processes or the design of systems.*

**Background**

In this document, we have set out an ambitious strategy to innovate and improve our DDaT services. We have intentionally set the bar high.

Delivering this strategy does not stop at the end of three years, but involves an iterative cycle of continuous improvement. Using agile methods and inquisitive feedback, we must define, build and then refine our services.

To innovate is to improve. Innovation may arise from the smallest change to a workflow or connecting two systems or databases through an API. It may also come from collaboration with colleagues across the health and care sector, participating in professional communities as well as maintaining an understanding of the potential for emerging technologies.

Continuous improvement is not limited to technology services. It must be an underlying part of our culture, processes and systems.
To achieve our ambition, we will

- Seek open and constructive feedback with our users through user research, satisfaction surveys, service reviews, and training and awareness sessions
- Make our responses to feedback part of an iterative process, so that improvements are monitored and refined continuously
- Use a lifecycle approach to system development and service management, seeking improvements at all stages, from defining a requirement to decommissioning
- Research developments in emerging technologies, such as artificial intelligence, automation, machine learning, for innovations relevant to the services we deliver
- Update our public facing content to better meet user needs and improve the user journey
- Ensure that the security of information, data and systems is at the heart of all of our DDaT services
- Ensure clear governance structures for digital programmes, including reporting, decision-making, and assurance
- Embed the HTA’s risk management framework and principles within all DDaT service activities
- Review this strategy annually

Measuring success

Measuring the level of use, quality and cost of our services supports our goal of continuous improvement.

We will measure the performance and effectiveness of our services through a combination of operational statistics, data analytics and, importantly, user feedback.

We will define our performance indicators to ensure that we determine:

- Whether the service is accessible, inclusive and meeting the needs of the user, by providing a positive and intuitive user experience, which enables them to complete tasks quickly and easily
- How well the platform is performing in terms of responsiveness, processing, uptime and availability
- Whether we are adding value, early and often, such as by contributing to the development of policy or delivery of operational initiatives
- The extent to which digital services enable policy delivery
Annex A – Example Business Process Model
Annex B – Scope of Data Management Body of Knowledge

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Annex E – Glossary

ITIL – ITIL is the IT Infrastructure Library and is a framework of best practices for delivering IT services.

COBIT – Control Objectives for Information and related Technologies; a business framework for the governance and management of enterprise IT.

SFIA – Skills Framework for the Information Age; a common reference model for people who manage or work in information systems related roles of any type describing professional skills at various levels of competence and responsibility.

BPMN – Business Process Model and Notation…

SaaS – Software as a Service

PaaS – Platform as a Service

IaaS – Infrastructure as a Service
Introduction

I am pleased to introduce this revised edition of the HTA People Strategy which will guide us over the period from 2019 to 2021.

The People Strategy remains a key document for the HTA, and sets out our commitment to you, and how through this commitment we can achieve success. Since the first Strategy was published in 2015, we have made a huge amount of progress against the goals we set ourselves. We have assessed the effectiveness of the approach through internal audit and via the staff survey and were heartened when both indicated that the focus on improving HTA staff experience was paying dividends.

This edition of the Strategy has undergone a more significant review. We have retained the core design of the original – which aims to link the successful achievement of the HTA’s goals through its people to the stages of the Employment Lifecycle Wheel.

While our core statutory responsibilities are unchanged, we will need to operate differently to succeed in a fast-changing environment where financial resources are constrained. With this in mind, the HTA has committed to a vision for 2021 which will focus on improving:

Sustainability - taking a new approach to recruiting high quality staff and developing the breadth and depth of expertise we require from them while working in new ways to reduce the pressures on the staff we have.

Resilience – developing our operating model to retain staff for longer and developing strategic alliances with other organisations to put us in a better position to manage unexpected demands.

Agility - providing a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells, while protecting public confidence and patient safety

We expect to achieve this vision through a transformation project which will improve our policies, processes and working practices, use our data and technology more effectively, and a shift to remote working by design.

All of these improvements will require your commitment to the vision and a willingness to embrace the opportunities presented by change. This edition of the Strategy emphasises what we will need to do differently, and what we need from you in order to deliver organisational transformation over the next two to three years.

I sincerely believe that the coming period will offer exciting opportunities to improve the services we offer to our stakeholders, make our jobs easier to do with better data and technology use, and provide development opportunities for all of us.

I look forward to working with you as we embark on these changes together.
Aim of this Strategy

The HTA’s overall strategic goal is to maintain and further enhance public confidence in the removal, storage and use of human tissue and organs by ensuring that it is undertaken safely and ethically, and with proper consent. We recognise that our people are our most important asset and are instrumental to our ability to achieve this goal. The Strategy sets out how we will lead and manage people and support their professional and personal development to ensure we have skilled and motivated people who we retain for longer, are proud to work at the HTA and are committed to achieving our organisational objectives.

A roadmap sits alongside this Strategy that provides the detail and a timeline of the actions we will deliver. Actions and their relative priorities are subject to staff views and will be reviewed and adjusted as part of business planning. This is to ensure the actions remain relevant to our people and aligned with our organisational objectives.

Objectives

This Strategy will be successful if we achieve four people objectives:

- To attract and retain the right people with the right skills
- To maintain the HTA’s positive working environment and culture, and uphold the values of the organisation.
- To lead, motivate, involve and support colleagues to deliver excellent work
- To improve expertise and support delivery through high quality learning and development

Employment Lifecycle Wheel

As part of this Strategy, an employment lifecycle wheel has been developed to identify each feature of organisational life that we experience during our time with the HTA. We believe our people, our ability to work as a team and our values are integral to everything we do and as such they form the core of our wheel, bringing together each of the categories.

We have aligned each of these categories with people objectives to ensure that the actions we take to deliver this Strategy will enhance our working experience and contribute to the delivery of our shared goals.
To attract and retain the right people with the right skills

Employment Lifecycle Category – Recruitment, Selection, Induction and Embedding

Why it matters

To achieve our goals, we need people who have the right skills and who are able to demonstrate the HTA’s values. This combined with an effective induction process that results in people feeling a part of our organisation and invested in achieving our goals, means we would be more likely to provide a higher level of expertise and achieve excellent results for our external stakeholders.

What we already do

The HTA has policies in place that underpin our recruitment, selection and induction processes. These processes have allowed us to recruit people with the right skills and experience, demonstrated by our high performing workforce. As a result of staff feedback, we have recently completed a project that redesigned and formalised our induction process. We are committed to continuing to work with our line managers to encourage a consistent approach to the delivery of our induction no matter which team or directorate you are joining.

We have a pay framework and job evaluation process that offers fair and competitive pay relative to similar organisations in the public sector and provides people with clarity on how starting and promotion pay is determined. We are transparent about public sector salary restrictions and advise all new starters of these at the time a job offer is made to ensure you can make a fully informed decision about joining the HTA.

How we will improve further

The capabilities needed for success over the coming years are likely to be different from those needed in the past. We will be more rigorous in assessing how vacancies could be filled to enhance our capabilities as posts become vacant. Recruitment has become more challenging with the financial constraints that have been in place and external factors indicate that recruitment is likely to become an even bigger challenge in the short to medium term. We will take a new approach to recruiting talent from a wider geographic pool, which will need to be supported by remote working by design and by a pay framework that is equitable for staff based in London and elsewhere in the country. This will also require us to further develop our induction model, to allow for our people and line managers to be inducted on a remote basis.

What you can expect

- A review of each post becoming vacant to ensure it best supports strengthened capability
- A review of the HTA pay framework to consider a London and National dimension
- Implementation of home workers contracts
- The induction process to remain under review and feedback to be sought from new starters
- Implementation of a remote induction model
- A formalised post-induction training programme for Regulation Managers
- Implementation of a competency framework

What we need from you

- To engage with the induction programme and provide support and guidance to new starters
- Actively participate in mentoring and induction initiatives
- Provide feedback on what is working well and where improvements can be made
- Take a proactive approach to introducing yourself to new starters including when working on a remote basis
Why it matters

With respect being one of our values, we understand how important it is that our people feel respected and valued for their contribution towards our achievements and recognition is an important part of this. In addition, we have a responsibility for the well-being of our staff and recognise that the HTA benefits greatly when people can establish and maintain an effective balance between their work and personal commitments.

What we already do

As an organisation within the public sector, we are constrained by the government’s restrictions on public sector pay increases. As such, the HTA is unable to provide increases in pay beyond these limits. This includes a restriction on offering incremental increases within salary bands based on length of service, on-the-job experience or additional qualifications gained since commencement in the position. However, the HTA does offer a generous annual leave entitlement including the option to buy and sell leave on two occasions per year as well as varied non-cash benefits including learning and development opportunities, wellbeing initiatives and access to the NHS pension scheme.

We are committed to the wellbeing of our people and offer flexible working arrangements to create a greater work/life balance, an employee assistance helpline, exercise subsidies and optional health assessments and vaccinations.

How we will improve further

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 staff. Evidence of this can be seen in the staff survey results which reported a third of staff feel unduly stressed at work. Our line managers have an instrumental role in ensuring we have a high performing workforce without detriment to our people’s wellbeing and work/life balance. We will work with our line managers to ensure they know how to recognise signs of stress within their team and how they can support their staff in the day to day management of this, including those staff who work remotely and are not physically present in an office.

What you can expect

- Better use of management information to plan and monitor workloads at the person level
- An action plan based on the recommendations of the HTA stress survey and audit
- Ongoing training and support for line managers and staff related to wellbeing
- Continuing promotion and development of the non-pay benefits we offer
- Recognition of long service within the HTA

What we need from you

- Seek clarification on any aspects of the HTA’s remuneration or benefits that you may be unsure of
- Actively participate in surveys and requests feedback
- Make suggestions for improvements to the available non-pay benefits options
- Recognise your colleagues’ contributions and good work
To maintain the HTA’s positive working environment and culture, and uphold the values of the organisation.

Employment Lifecycle Category – Culture and Environment

Why it matters

Everyone should expect to have facilities and equipment, be that in a physical office or working on a remote basis that will allow each person to deliver their objectives effectively. The HTA also has agreed values which we believe will promote a culture and positive team working environment within the organisation, where everyone is shown respect and everyone’s contribution to our success is recognised. Having the right work environment and culture allows everyone to perform to the best of their abilities.

What we already do

We have a set of core values that underpin the way in which we conduct ourselves, perform our roles and interact with each other and external stakeholders. In addition, we have policies in place that protect staff who wish to make a complaint or may be vulnerable. Feedback from staff surveys suggests that there is a positive working environment at the HTA where people feel supported by their colleagues. People also feel that their colleagues demonstrate the HTA’s values, but ways to ensure that the values remain alive and embedded within our culture, particularly with a shift towards more remote working, should be explored.

We invest in business technology which is regularly upgraded for greater functionality and provide opportunities for staff to work flexibly which feedback suggests offers an increased level of positive work/life balance.

How we will improve further

Half of the HTA’s workforce now work predominately from home, and based on feedback from staff, we believe this is likely to increase in the short to medium term. We are starting to move towards having more formal mechanisms in place to support home-based working; this includes equipment, policies and appropriate assessment of the home-working environment. In addition, our current accommodation lease expires in 2021 with Government policy require ALB’s to relocate to locations outside of central London. These two factors will have an impact on our working environment and our overall organisational culture.

We are committed to consulting with staff through this period to develop policies, systems and process that will support our change in working environment. This includes ensuring that staff who may remain based within an office environment do not feel isolated or disconnected from their colleagues who do work on a remote basis.

What you can expect

- Relocation of the HTA office from 151 Buckingham Palace Road
- Consultation and regular communication on our office move
- Prioritisation of investment in telephony and video conferencing to support remote working
- More concrete guidance to support home-based working including a best practice guide
- More frequent face-to-face corporate days to promote the HTA culture
- Promotion of our policies with regular staff feedback on their effectiveness
- A re-assessment of our values framework to ensure it suits our new way of working
HTA (07c/19) Annex C People Strategy 2019-21

What we need from you

- Participate in training to make better use of business technology
- Engage with consultation and communication opportunities
- Demonstrate the HTA values through your work and interactions with each other and external stakeholders
- Challenge behaviour that does not match with our organisational values
- Be aware of the HTA policies and seek clarification to gain a better understanding where required
- Make suggestions for improvements where policies could be more effective
- Participate in staff surveys
Employment Lifecycle Category – Involvement and Communication:

Why it matters

To be successful we need everyone to be committed to our organisation’s values and goals and understand how they fit into achieving these. Everyone should expect to receive transparent information about decisions and developments relevant to their job and about relevant changes in the HTA’s wider environment.

What we already do

Feedback suggests that generally our people are positively involved with the HTA. In particular, there is an appreciation of the important purpose of the organisation. We have a wide variety of mechanisms for communicating information and receiving feedback. These include a weekly staff newsletter, team cascades, all staff meetings, Monday briefings, awaydays, line manager 1-2-1s, the staff survey and the staff forum. All staff are also given opportunities to attend decision making meetings as observers.

In addition, there are opportunities for staff to interact with our Authority Members, to increase our understanding of the role Members carry out for the organisation and to further build relationships between Members and staff.

What we will do to improve further

With more people working remotely, we will need to develop new mechanisms for communicating information and receiving feedback that is inclusive of all working arrangements.

Business technology will play a key role in how we ensure we continue to have transparent, effective and consistent communication practices across the full organisation. This will include regular opportunities to bring staff together such as all staff meetings.

What you can expect

- New mechanisms for communicating information and receiving feedback
- Better use of business technology to stay in touch when working remotely
- Promotion of opportunities to observe SMT, HTAMG and Authority meetings
- Quarterly all staff away days and all staff meetings in the intervening months

What we need from you

- Participate in methods to stay in touch including reading the weekly newsletter
- Engage with different types of business technology and provide feedback
- Actively participate in the opportunities for all staff to come together
- Make suggestions for improvements where communication could be more effective
- Participate in the staff forum if you want to have your voice heard
To lead, motivate, involve and support colleagues to deliver excellent work

**Employment Lifecycle Category – Inspire and Motivate**

**Why it matters**

Our line managers play an essential role in inspiring, motivating and providing clear direction for projects, teams and the organisation as a whole. This ensures that everyone working at the HTA understands our goals and contributes all they can to achieving them. Being able to communicate this consistently and being available to provide clarity when it is needed are critical to this. We know our people believe in the importance of the HTA’s work and the value we provide to our stakeholders. This is the most powerful motivator we have, so providing our people with well-designed roles, development opportunities and ensuring people’s expertise is considered and used in designing future plans is critical to us achieving excellence.

**What we already do**

We have a number of practices in place to provide leaders and managers with an opportunity to inspire and motivate their teams. These include regular 1-2-1s, team meetings and the PDP process all of which offer opportunities to provide direction and celebrate success. We encourage our managers to undertake training and/or coaching to assist them in further developing their skills and techniques. We also recognise that not everyone has ambitions to be in a management role and will look for opportunities that allow people to further develop expertise in key areas of interest to them.

**What we will do to improve further**

The flexible use of people will be key to delivering our objectives and ensure that we are able to allocate resource where it is needed. The transformation programme will provide increased opportunities for our people to develop skills in new areas such as process redesign and the use of new technology. For this to be a success, we will need to ensure that all of our staff understand the principles of a matrix approach to using people resources and feel able to engage and work in this way.

In addition, we will work with our line managers and staff to identify ways to strengthen relationships and ensure opportunities to provide direction and celebrate success is not lost as a result of less face-to-face contact.

**What you can expect**

- Continued communication from, and visibility of, the Senior Management Team
- Better use of business technology to support communication practices when working remotely
- Communication of information transparently and consistently by adopting a common standard for team meetings and cascades
- Development and sharing of good practice amongst line managers

**What we need from you**

- Proactively engage with the support, tools and training made available to further develop leadership skills and techniques as well as greater expertise in areas of individual interest
- Be committed to the PDP process and ensure that it is undertaken in a way that adds value to both you as a manager, your team and the HTA as a whole.
- Make suggestions for improvements where communication from all levels of the organisations management could be more effective.
- Proactively engage in initiatives aimed at increasing communication between staff and SMT
To lead, motivate, involve and support colleagues to deliver excellent work

Employment Lifecycle Category – Managing for High Performance

Why it matters

We believe that effective, regular dialogue between managers and their teams is one of the most critical elements in achieving our objectives. All of our people, at every level within the organisation, should expect clarity on what is expected of them, regular feedback on their performance both when they have been successful and when development is needed. It is through these discussions that our managers will assist their people to identify development and/or progression opportunities that allow them to grow both professionally and personally within their roles and the organisation.

Alongside traditional line management, project management skills will become increasingly important as we embark on the transformation programme.

What is already have in place

There are a number of policies and processes in place that ensure a consistent and fair approach to the management of our people. All line managers attend management training to equip them with the tools they need to be able to identify skills, strengths and development opportunities as well as hold effective conversations with their teams about performance, workload planning and development opportunities.

We acknowledge that everyone will have individual development needs that require different support and we work with our people to identify and manage these needs as part of the annual performance development plan (PDP) review, six monthly reviews of progress and regular 1-2-1 meetings. Based on the outcomes of these regular reviews, we offer a wide variety of learning and development opportunities.

What we will do to improve further

We will continue to grow the expertise of our line managers, ensuring that staff are receiving regular feedback on their performance, where they have been successful and where development is needed. This will be even more important in instances of remote working to ensure staff continue to feel engaged and connected to the organisation. In addition, we will improve the use of management information, allowing us to actively manage workloads and to identify support and development needs.

Achieving organisational transformation to time, cost and quality constraints, alongside business as usual will require a more rigorous approach to project and change management. This will be supported by appropriate processes and training, and enhanced accountability to the programme board for senior responsible owners.

What you can expect

- Training on HTA project roles, processes and assurance mechanisms
- Increased scrutiny of business plan and programme outcomes by SMT and the Programme Board
- Managers continuing to undertake regular 1-2-1’s with all members of their teams
- Maintaining a regular programme of management training and development opportunities
- Assistance for managers to ensure their team is equipped with the necessary tools and skills

What we need from you

- Actively participate and engage in your PDP, progress reviews and 1-2-1 meetings including identifying your own development needs and taking responsibility for achieving them
- Provide feedback to your manager where you feel communication, workload management or procedures could be improved
- Commitment to project management processes and assurance mechanisms
Why it matters

We believe that we will make better decisions and deliver better quality regulation if we have an organisation which can draw on different personal and professional backgrounds and perspectives. As an employer, we are committed to fostering a respectful and transparent culture that promotes equality and inclusion.

What we already do

We have a number of policies and procedures in place that ensure the ways in which we recruit, develop and manage our people are free from practices that may lead to discrimination. We are committed to supporting our line managers and people in understanding equality issues through a range of training opportunities as well as undertaking regular monitoring of our practices. This includes an annual equal opportunities audit with results communicated to the organisation. We also ensure that all internal opportunities are communicated in an open and consistent manner.

What we will do to improve further

We receive positive feedback from both employees and candidates throughout the recruitment process which suggests that the HTA offers an inclusive environment where people are treated equally, with respect and where each individual’s skills and experiences are valued.

We will ensure that equality considerations are reflected in the design of our policies and the delivery of services, this includes internal policies. We are also committed to continuing to deliver training on equality issues.

What you can expect

- Policies that guide and monitor our practices to ensure equality and diversity within our organisation are promoted
- An annual equal opportunities report to ensure our selection processes align with our commitment to equality and diversity
- All staff will continue to be made aware of all vacancies within the HTA and given the opportunity to express interest and apply
- Diversity statistics reported annually as part of the Annual Report and Accounts
- Further equality and diversity and unconscious bias training

What we need you to do

- Actively participate in creating an inclusive environment in which people feel both respected and valued
- Comply with the HTA Equality, Diversity and Human Rights Policy including notifying managers, SMT or HR of any misconduct taking place within the organisation
To improve expertise and support delivery through high quality learning and development

Employment Lifecycle Category – Learning and Development

Why it matters

Effective learning and development opportunities will assist in building the confidence that our people need to make key decisions and use initiative when delivering our statutory remit.

Providing access to learning and development opportunities will allow for continuous improvement of job specific skills and knowledge as well as personal development, both of which will support the ongoing growth, professional development and success of our people.

Transformation of our processes and technology need to be supported by effective training to realise the business benefits envisaged.

What we already do

We offer a wide variety of learning and development opportunities to our people as part of our learning and development framework, including job-specific training, mentoring, coaching and a career investment scheme which is aimed at providing our people with the opportunity to undertake training which will enhance their personal development. Our people are encouraged to provide input to the type of training we offer and engage with our training providers in developing course outlines. Our commitment to offering these opportunities has resulted in a strong track record of appointing and promoting from within our organisation when an opportunity has become available.

What we will do to improve further

Our people often highlight our learning and development opportunities as a key benefit to working at the HTA. The quality and relevance of the training offered also continues to improve through increased involvement with our people and training providers.

We will develop a training programme that enables us to provide a more structured approach to job specific development, allowing us to maintain the level of quality and consistency required to deliver better regulation. Changes to our physical presence will affect the way in which we bring staff together for learning and development opportunities. We will need to consider how we can best use technology to deliver training opportunities in the future.

What you can expect

- A baseline training needs analysis and guidance on effective and structured development discussions
- The introduction of a programme of ongoing refresher training for all staff in key business processes
- Assessment of a business case for a permanent in-house training function
- Providing managers with increased support and knowledge to be able to assist their staff to actively manage their learning and development needs
- Encouraging professional development through conferences and event attendance
- Exploration of external Talent Management opportunities
- Enhancing our sector specific training to ensure staff working across all sectors are equipped with the information and knowledge they need to be successful

What we need from you

- Take ownership of your own personal and career development needs.
- Actively prepare for and participate in the PDP process.
- Provide feedback and input to the training and development opportunities delivered.
Measuring Effectiveness

As part of our commitment to our people and this strategy, it is important that we are able to track and demonstrate our progress towards achieving success.

To do this we will:

- Complete an internal audit that assesses the impact and effectiveness of this strategy and our people practices
- Seek to demonstrate the link between HR indicators of success and the achievement of our organisational objectives
- Gain feedback and report back to the Authority, SMT and staff on the initiatives delivered as part of this strategy
Authority Standing Orders Update and Amendment

Purpose of paper

1. This paper presents proposed amendments to the Authority’s Standing Orders in the following regards:
   
   - Minor amendments to the Audit Risk and Assurance Committee terms of reference (TOR) (Annex 2, Appendix 3, Section A)

Decision-making to date

2. The Audit Risk and Assurance Committee (ARAC) reviewed and approved minor updates to the ARAC members’ handbook including the ARAC terms of reference at its meeting in October 2018.

Action required

3. Members are asked to approve the amendment to the ARAC terms of reference to allow the Standing Orders to be updated. A copy of the amended terms of reference are provided in Annex A, with updates highlighted in red.
Section 2

Terms of reference of the Audit & Risk Assurance Committee

Constitution

1. The Authority has established an Audit and Risk Assurance Committee (known to Human Tissue Authority (HTA) staff as ARAC) to support it in its responsibilities for risk management and governance. The ARAC will achieve this by advising the Authority and the Accounting Officer on the exercise of their responsibilities, ensuring the comprehensiveness of assurances that these responsibilities are being met and reviewing the reliability and integrity of these assurances.

2. The ARAC will make recommendations to the Authority regarding the adoption of the Annual Report and Accounts.

Duties and functions

3. The ARAC will advise the Accounting Officer and Authority on:

   a) the strategic processes for risk, control and governance and the Annual Governance Statement;
   b) the accounting policies, the accounts, and the annual reports of the HTA. This includes the process for review of the accounts prior to submission for audit, levels of error identified, and management’s letter of representation to External Audit;
   c) the planned activity and results of both Internal and External Audit;
   d) adequacy of management response to issues identified by audit activity, including External Audit’s audit completion report;
   e) assurance relating to corporate governance requirements for the HTA;
   f) the remuneration report for staff and Members as presented in the annual report and accounts
   g) (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non-audit services from contractors who provide audit services; and
   h) where necessary, anti-fraud policies, whistle-blowing processes, organisational culture and arrangements for special investigations.

Rights

4. The ARAC has the following rights:

   a) it may co-opt additional participants, for a period not exceeding a year, to provide specialist skills, knowledge and experience (these additional participants must be recruited in line with paragraph 15 of this document);
   b) it may procure independent specialist ad-hoc advice, at the expense of the HTA, subject to budgets agreed by the Authority; and
   c) it may seek any information it requires from HTA staff, who are expected to assist the Committee in the conduct of any enquiries.
Access

5. Internal and External Audit will have free and confidential access to the Chair of the ARAC. In addition, a confidential session with Internal and External Auditors for ARAC members will be scheduled each year.

Information requirements

6. As appropriate to the meeting the ARAC will be provided with:

   a) a report summarising any significant changes to the organisation’s Risk Register;
   b) a progress report from Internal Audit summarising: work performed (and a comparison with work planned); key issues emerging from Internal Audit work;
   c) management response to audit recommendations;
   d) changes to the Internal Audit Plan;
   e) details of any resourcing issues affecting the delivery of Internal Audit objectives. Requests for work and reports received will be channelled through the Accounting Officer, to whom Internal Audit reports;
   f) a progress report from the External Audit representative summarising work done and emerging findings; and
   g) progress reports from the Executive, including periodic in-depth reports on areas of potential uncontrolled risk as identified by the ARAC.

7. As and when appropriate the ARAC will also be provided with:

   a) the Internal Audit Plan;
   b) Internal Audit’s annual opinion and report;
   c) External Audit’s annual report and opinion
   d) the draft accounts of the organisation;
   e) the draft Annual Governance Statement;
   f) a report on any changes to accounting policies;
   g) a report on any proposals to tender for audit functions;
   h) a report on co-operation between Internal and External Audit; and
   i) a report on any fraud or financial misdemeanour and any whistleblowing.

Reporting to the Authority

8. The Authority will receive the minutes of meetings of the ARAC for information. The circulation of any confidential minutes will be at the discretion of the Committee Chair.

9. The ARAC will formally report back (either verbally or in writing) to the Authority after each of its meetings.
10. The ARAC will provide the Authority with an Annual Report, timed to support the finalisation of the accounts and the Annual Governance Statement. The report will summarise the conclusions from the work it has undertaken during the year.
Reviewing effectiveness

11. The ARAC will undertake annual reviews of its own effectiveness and agree actions for improvement based on the National Audit Office’s self-assessment checklist for Audit Committees. The ARAC will report the results of the review to the Authority.

Recruitment and membership

12. The ARAC will be chaired by a lay Authority Member, who is not the Authority Chair, and who preferably has relevant experience and expertise.

13. All other members of the Committee should be Authority Members, but not Authority Chair. Including the ARAC Chair, there will be a minimum of three Authority Members and a maximum of five Authority Members on the Committee at any time.

14. At least one Authority Member, who is not the ARAC Chair, must be a member of both the ARAC and the Remuneration Committee, to provide assurance over remuneration matters.

15. Recruitment of Authority Members to the ARAC will be through ‘expressions of interest’ with personal statements in application. The applications will be reviewed by the Authority Chair and the Chief Executive, who will decide on the appointments. Should an insufficient number of expressions of interest be received to fill an available role, the Authority Chair will appoint the Member who has the most appropriate skills and experience to the role.

16. The ARAC Chair and the other ARAC members will be appointed for a set term of three years, which will not exceed their tenure as Authority Members. It should be noted that Authority Members may be reappointed to the ARAC in accordance with the HTA’s business needs.

17. Members of the ARAC must disclose the existence and nature of any personal or material interest before the discussion of that interest at any meeting. They must be free of any relationship that may compromise their independence or interfere with the exercise of their judgement.

Attendance

18. A minimum of two members of the ARAC (excluding the ARAC Chair) will be present for the meeting to be deemed quorate.

19. Committee members will be expected to attend every meeting. If a member is not able to attend a meeting they must provide apologies to the Secretary in advance of the meeting if possible. If a member does not attend more than two consecutive meetings the Committee Chair will arrange a meeting with the
member to discuss their attendance and whether they wish to continue their membership of the Committee.

20. Authority Members who are not members of the ARAC have the right of attendance at Committee meetings. Authority Members attending meetings shall be entitled to speak with the permission of the Chair of the meeting, but in no case shall they be entitled to vote.

21. If the ARAC Chair is not present at a meeting, an alternative Authority member will be co-opted to chair that meeting.

22. The Chair of the Authority may attend Committee meetings, say once per year and not so frequently as to compromise the independence of the Committee. An Authority Member who is not a member of the ARAC may be co-opted as a member of the ARAC for a specific meeting if necessary to ensure a meeting is quorate.

23. The Chief Executive in his or her role as Accounting Officer (as defined in the Framework Agreement), the Director of Resources, and any other officer (at the discretion of the Chair) and Internal and External Audit (or equivalents) will also attend meetings of the Committee.

24. Up to two observers from the Department of Health and Social Care will normally be invited to attend meetings of the Committee.

25. The ARAC may ask any other officials of the Authority to attend to assist it with its discussions on any particular matter.

26. The ARAC may ask any or all of those who normally attend but who are not members to withdraw to facilitate open and frank discussion of particular matters by the Committee.

**Frequency of meetings**

27. The ARAC will meet three times per calendar year, with meetings timed to ensure effective and timely conduct of business and reporting to the Authority.

28. The Chair of the ARAC may convene additional meetings, as they deem necessary.

29. External Audit may request a meeting of the Committee if they consider one necessary.

30. The Accounting Officer or the Authority may ask the ARAC to convene further meetings to discuss particular issues on which the Committee’s advice is sought.

**Secretariat responsibilities**

31. The Board Secretary will have secretariat responsibility for the Committee.
32. The Secretary must ensure Committee meeting dates are scheduled, meeting venues are booked and that Committee members are invited to attend all meetings.

33. The Secretary will liaise with the Committee Chair to create the agenda and will be responsible for collating and distributing the papers relating to the meeting. The agenda, minutes from the last meeting and the meeting papers for consideration will be distributed to the Committee one week before each meeting.

34. The Secretary will be responsible for taking minutes of meetings and recording action points. The draft minutes and action points from each meeting will be circulated as soon as possible, within one month of the meeting. Committee members will be asked to provide any comments on accuracy of the minutes by email within a time frame set by the ARAC Chair. This will ensure the key areas of discussion and action points are captured accurately.

35. The minutes will be approved by the ARAC 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.

36. The Secretary will write a short summary of the issues discussed at each meeting for publication in the next staff newsletter and e-newsletter. This note will be drafted within one week of each meeting and approved by the Committee’s Chair prior to being sent to the Head of Communications for publication.
Version history

37. These Terms of Reference will be reviewed annually by the ARAC and will be approved by the Authority following that review.

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