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

Eighty-fifth Meeting of the Human Tissue Authority

Date 19 July 2018
Time 10.00 – 16.00
Venue Orient Suite
Grosvenor Hotel, 101 Buckingham Palace Rd, London SW1W 0SJ

Agenda

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Welcome and apologies</td>
<td>10.00</td>
</tr>
<tr>
<td>2.</td>
<td>Declarations of interest</td>
<td>Oral</td>
</tr>
<tr>
<td>3.</td>
<td>Minutes of 10 May 2018</td>
<td>HTA (19/18)</td>
</tr>
<tr>
<td>4.</td>
<td>Matters arising from 10 May 2018</td>
<td>Oral</td>
</tr>
</tbody>
</table>

**Regular Reporting**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>5.</td>
<td>Chair’s Report</td>
<td>Oral</td>
</tr>
<tr>
<td>6.</td>
<td>Chief Executive’s Report</td>
<td>HTA (20/18)</td>
</tr>
<tr>
<td>7.</td>
<td>Delivery Report – Quarter One 2018/19</td>
<td>HTA (21/18)</td>
</tr>
<tr>
<td>8.</td>
<td>Development Report – Quarter One 2018/19</td>
<td>HTA (22/18)</td>
</tr>
<tr>
<td>9.</td>
<td>Deployment Report – Quarter One 2018/19</td>
<td>HTA (23/18)</td>
</tr>
</tbody>
</table>

**Committee and Advisory Group Reporting**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>10.</td>
<td>Audit and Risk Assurance Committee Update</td>
<td>HTA (24/18)</td>
</tr>
<tr>
<td>11.</td>
<td>Transplantation Advisory Group Update</td>
<td>HTA (25/18)</td>
</tr>
<tr>
<td>12.</td>
<td>Histopathology Working Group Update</td>
<td>HTA (26/18)</td>
</tr>
</tbody>
</table>

**Strategy**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>13.</td>
<td>Routemap to 2021</td>
<td>Oral</td>
</tr>
</tbody>
</table>

**Policy Issues**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>15.</td>
<td>HTA Policy for managing and referring potential criminal breaches of Human Tissue legislation</td>
<td>HTA (28/18)</td>
</tr>
<tr>
<td><strong>Other Items</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>Question and answer session</td>
<td>Oral</td>
</tr>
<tr>
<td>17.</td>
<td>Any other business</td>
<td></td>
</tr>
</tbody>
</table>

Meeting close 12.45  
Lunch: 12:45 – 13:30 (not public)  
Afternoon training session (not public) 13:30 – 15:00
Minutes of the eighty-fourth meeting of the Human Tissue Authority

Date 10 May 2018
Venue Viceroy Suite, Grosvenor Hotel
101 Buckingham Palace Road
SW1W 0SJ

Present

Members
Nicola Blackwood (Chair)
Dr. Hossam Abdalla
Dr. Stuart Dollow
Amanda Gibbon
Prof. Andrew (Andy) Hall
William (Bill) Horne
Glenn Houston
Prof. Penney Lewis
Prof. Dame Sally Macintyre
Prof. Anthony Warrens

Apologies
Bishop Graham Usher
Dr. Lorna Williamson, OBE

In attendance
Allan Marriott-Smith (Chief Executive)
Christopher Birkett (Interim Director of Regulation)
Dr. Hazel Lofty (Director of Policy, Strategy and Communications)
Richard Sydee (Director of Resources)
Kevin Wellard (Quality and Corporate Governance Manager)
Jessica Porter (Head of Regulation) (Item 14)
Dr. Amy Thomas (Interim Head of Regulatory Development) (Item 15)

Observers
Lucy Foster (Department of Health and Social Care)
Nicolette (Nicky) Harrison
<table>
<thead>
<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item 1</td>
<td>Welcome and apologies</td>
<td>1. Nicola Blackwood (the Chair) welcomed Members, attendees and observers to the eighty-fourth meeting of the Human Tissue Authority (HTA).</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. The Chair noted that Lucy Foster would observe the meeting from the Department of Health and Social Care (DHSC). The Chair noted that Nicolette Harrison would also observe the meeting. Nicolette Harrison had recently been appointed as the Director of Regulatory Delivery and was due to join the HTA in June 2018.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3. The Chair advised that Jessica Porter (Head of Regulation) would join the meeting to present Item 14 – an update on the opt-out proposal for deceased organ donation in England [paper HTA (17/18)]. Dr. Amy Thomas (Interim Head of Regulatory Development) would also join the meeting to provide an update on the implementation of the Coding and Import Directives (Item 15) – [paper HTA (18/18)].</td>
</tr>
<tr>
<td>Item 2</td>
<td>Apologies</td>
<td>4. Apologies for absence were received from Authority Members Bishop Graham Usher and Dr. Lorna Williamson, OBE and Jeremy Mean from the DHSC.</td>
</tr>
<tr>
<td>Item 3</td>
<td>Declarations of interest – Oral</td>
<td>5. 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.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6. The Chair congratulated Dr. Stuart Dollow on having recently been appointed as the Chair of the Advisory Committee on Clinical Excellence Awards. Dr. Dollow advised the meeting that he would be relinquishing his post as the Head of Global Clinical Development and Medical Affairs at UCB.</td>
</tr>
<tr>
<td>Item 4</td>
<td>Minutes of 8 February 2018 – HTA (11/18) and HTA (c12/18)</td>
<td>7. Ahead of the meeting, Members were asked to provide comments on the minutes of the Authority meeting on 8</td>
</tr>
</tbody>
</table>
February 2018. The Chair advised that comments had been provided by Amanda Gibbon and had been incorporated into the draft minutes, which had been circulated in advance of this meeting.

8. The minutes were accepted as an accurate record of the meeting.

<table>
<thead>
<tr>
<th>Item 5</th>
<th>Matters arising from 8 February 2018 – Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>The Chair noted that all actions from the 8 February 2018 Authority meeting were resolved, ongoing in nature or would be addressed by the Senior Management Team (SMT) during the meeting.</td>
</tr>
<tr>
<td>10.</td>
<td>The Chair asked Members for any further matters arising; none were raised.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 6</th>
<th>Chair’s Report – Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>The Chair informed the meeting that her introductory meetings with SMT members and Heads were underway. The Chair advised that she had also completed her initial living organ donation assessment training and, working with the Communications Team, had mapped key stakeholders to inform with letters of introduction and face-to-face meetings.</td>
</tr>
<tr>
<td>12.</td>
<td>The Chair also said that she had met or spoken with the majority of Members and she fed back some of the key points that had been raised in advance of the meeting:</td>
</tr>
</tbody>
</table>

- The Chair announced that she had considered comments from Members concerning the new Committee and Advisory Group structure and how it could be further improved. Members were advised that the Chair would undertake further discussions with a view to finalising structures in the near future.

- As part of GDPR readiness and in line with best practice, the HTA was working through a number of issues including the security of emails. This included the use of non-HTA email addresses for HTA communications. Full guidance would be issued in due course but as a first step, Members had received instructions with their packs on the installation of the Blackberry ‘Work’ app on to their personal devices.
Members were informed that this would enable them access to their HTA accounts and that further guidance on this process and email security more generally was available from Dave Thomson, the HTA’s Head of Business Technology.

- Members had suggested a forward planner to inform future post-meeting training sessions. A list of proposed training topics was tabled by Dr. Hazel Lofty. Members agreed to discuss this matter further under the any other business item of the agenda.

**Action 1: Members consider the installation of the Blackberry Work application on their personal mobile devices to facilitate access to their HTA email accounts.**

**Item 7  Chief Executive’s Report – HTA (11/18)**

13. Allan Marriott-Smith presented this item and introduced the report.

14. Members were advised that the SMT had attended a quarterly accountability meeting with the DHSC on 24 April 2018. The meeting also served as the end of year review of the HTA’s achievements, year-end financial position and progress against its Key Performance Indicators (KPIs). The SMT had also outlined the HTA’s priorities for 2018/19, the operational risks of the previous quarter and set out a projection of strategic risks for the coming year.

15. Allan Marriott-Smith asked Members to note his gratitude to staff whilst considering the HTA achievements throughout the 2017/18 business year. Members were informed that despite a challenging year, which had involved budgetary constraints, the strategic review, organisational changes and higher than usual levels of staff turnover, the HTA’s achievements included:

- The completion of 240 site visits against a target of 210;
- A positive response to the 2017/18 staff survey;
- Implementation of the Import and Coding Directives;
- Completion of user testing phase of the Customer Relationship Management System upgrade; and
- A year-end budget surplus.
16. Members were advised that the Department had taken assurance from the information provided at the meeting and that no significant issues were raised. Allan Marriott-Smith informed the meeting that, subject to DHSC approval, he expected the HTA Strategy and 2018/19 Business plan to be published within the following two weeks.

17. Members noted their receipt of the minutes of the January accountability meeting. Bill Horne queried the rationale for the HTA sharing details of findings from inspections in Wales with the DHSC, given that the establishment in question was not within the Department’s remit. Members were advised that the SMT informs the Departmental sponsor team of any high profile findings, regardless of geographical area, for the mitigation of potential reputational risks to the HTA.

18. Allan Marriott-Smith advised Members that he had recently met individually with each member of the HTA’s staff. The purpose of the meetings was to seek staff views on the proposed revisions to the organisation’s structure and what the HTA, and in particular the SMT, needed to do to improve. The key themes arising from the meeting were:

- broad support for the proposed structure, including the consideration of new senior inspector roles, albeit with recognition that the introduction of this new role could cause friction between staff;
- the need to address the recent increase in critical and major shortfalls;
- a need to improve the processes for inducting new Regulation Managers (RMs);
- a need to develop and maintain the organisation’s quality management systems; and
- concern that the HTA’s approach to regulation was overly consultative or not firm enough.

19. Members asked for more detail and further assurance on the Executive’s intended response to the staff perception that the HTA was too consultative in its approach to regulation. Allan Marriott-Smith advised that the concerns had arisen from a perceived lack of preparedness of establishments during inspections. This was despite pre-inspection activity having been undertaken by RMs. Staff had also questioned the
ongoing sustainability of continuing to lead establishments through corrective measures at the current levels of intensity.

20. Members were advised, however, that these perceptions would be subjected to further investigation and root cause analysis. Members were also given assurance that any resulting changes in the HTA’s approach to regulation would be evidence based.

21. Members were advised that the Executive had twice needed to utilise the HTA Critical Incident Response Plan (CIRP) during quarter four. The plan had first been deployed because of a power failure at the HTA office. A ‘lessons learnt’ exercise was undertaken shortly after the incident and a full report will be made to the Audit and Risk Assurance Committee at its meeting on 19 June 2018.

22. The second occasion was in response to an HTA licensed establishment going into administration. Members were advised that although this incident concerned issues on the margins of the HTA’s remit, it had nevertheless posed a risk to public confidence. The substance of this event was reported as part of the Delivery report and was being managed in accordance with the CIRP. It was agreed that the Audit and Risk Assurance Committee (ARAC) should receive an interim report on this item at its meeting on 19 June 2018.

23. Prof. Andy Hall commended the Executive for its hard work and ongoing containment of risks in preventing further incidents from developing into critical incidents.

24. Members welcomed the Executive’s plans to separate the public Authority meeting from the annual conference, but asked for further detail on the reasons for this approach. Allan Marriott-Smith advised that the changes would enable the HTA to deliver better focussed interaction with stakeholders at future conferences.

25. Members were advised that the HTA had yet to receive the Pay Remit for 2018. Members were assured that they would receive an update on this issue once the details of the remit had been confirmed.
26. Members asked for details on the single complaint received during quarter four. The Authority was informed that the complaint had arisen due to the HTA’s failing to respond to a single FOI request on two occasions. Members were advised that the incident was due to a known systems issue and had identified a staff training need, which had since been addressed. Members were given assurance that the matter had been resolved to the satisfaction of the complainant.

27. Members were referred to the Strategic Risk Register [Paper HTA (11/18) Annex A] and advised that the SMT had recently undertaken its annual review of strategic risks. Allan Marriott-Smith highlighted that the SMT were considering the introduction of a sixth risk, later in the year, to reflect the strategic risks associated with the HTA’s transition towards the implementation of the new strategy and business plan. Members noted the register pending an amendment of the residual risk colour indicator for risk two, from green to yellow.

28. The Authority noted the content of this report.

Action 2: The SMT to amend the residual risk colour indicator for risk two within the Strategic Risk Register from green to yellow

Action 3: the ARAC to receive an interim report on the HTA licensed establishment going into administration and use of the CIRP due to a power outage at 151 Buckingham Palace Road

Item 8 Delivery Report – Quarter Four– HTA (14/18)

29. Christopher Birkett presented this item and introduced the report.

30. Members were informed that, despite undertaking a reduced inspection workload, quarter four had been extremely busy for business-as-usual activities. This was reflected in the number of Regulatory Decision Meetings that were needed (seven in quarter four compared with two in quarter three) and the increase in enquiries (1054 in quarter four compared with 794 in quarter 3).

31. Christopher Birkett also advised the Authority that, although
there had not been any critical shortfalls identified during quarter four, the number and severity of shortfalls in the Post Mortem (PM) sector remained a concern. Members were advised that, during the 2017/18 business year, 500 shortfalls had been identified within the PM sector compared with 54 the previous year. Members were informed that this had had a significant impact on the length of PM inspections and the post-inspection workload.

32. Members were given assurance that in addition to the proposed improvements arising from ongoing PM sector development work, the Executive was also reviewing the post-inspection process, to reduce the workload on Regulation Managers.

33. The Authority was informed that there had been two new investigations during quarter four.

34. The first investigation arose from the HTA receiving an anonymous allegation concerning the inappropriate storage of bodies at two post mortem establishments. Members were advised that the investigation had now been closed following receipt of satisfactory assurances from one of the establishments and having visited and issued guidance to the other establishment.

35. Members were informed that the HTA was investigating concerns that were raised in relation to two related HTA-licensed establishments, which had recently entered into administration.

36. Members asked for assurance on the status of cells stored by these organisations. Members were advised that one of the establishments did not directly store cells and that the HTA had intervened to facilitate the movement of cells held by the other establishment to a safe third-party site.

37. Members were informed that the HTA would continue to work with the establishments and administrators to ensure that samples and records are maintained and stored safely and that clients would be contacted as appropriate. Members asked the Executive to consider the lessons learned from this investigation to inform the HTA Critical Incident response.
Members were further advised that, during quarter four, the HTA had issued Directions to each of these establishments, prior to their going into administration. The SMT was also due to consider the prospective referral of any potential breaches of legislation to the police.

Members commended the Executive for keeping them informed on this issue.

Members also congratulated the Executive on the HTA’s successful implementation of the European Union (EU) Coding and Import Directives.

Christopher Birkett informed the meeting that the HTA had recently surveyed public and professional stakeholders on their usage of the HTA website. The survey received 738 responses, of which, 75% came from members of the public, 14% from professionals working at HTA licensed establishments, 3% from medical professionals, and 8% from ‘Other’ respondents.

Members were advised that the majority of public users believed that the HTA website met their needs ‘very or extremely well’. Most public users (83%) said that they would recommend the HTA website to a friend or colleague.

Most professional users found it ‘quite or very easy’ to find what they were looking for but, 23% do not find it easy to locate the information they required.

Members were provided with an update on the HTA’s performance against key performance indicator two: ‘100% of Corrective and Preventative Actions (CAPAs) implemented to address major and critical shortfalls are completed to the HTA’s satisfaction within agreed timescales or further regulatory action implemented’. The Authority was informed that, whereas the status of this indicator had remained red throughout quarter four, performance had improved compared to the previous quarter. In March 2018, 16 out of 17 major and critical shortfalls had been completed on time.
45. Members discussed the need for the HTA to share, with establishments, the insights and learning arising from the HTA Reportable Incidents (HTARIs) in the post-mortem sector that are reported in table two of the delivery report. Members were advised that the SMT was considering the inclusion of such information within the annual patient safety report that was due to be presented to the Authority at its meeting on 19 July 2018. Members were provided with assurance that the learning contained within the report would then be circulated in an appropriate format to establishments.

46. Christopher Birkett commented on the apparent increase in Serious Adverse Events and Adverse Reactions (SAEARs) linked to processing, that are reported in table three of the delivery report. Christopher Birkett advised the Authority these events were mostly due to potential contamination of samples but stressed that there were no material underlying issues to report at this stage. Members were informed that the HA team would keep this under review as part of annual reporting to the EU. Members asked for clearer detail in the future descriptions of the individual SAEARs, which are routinely reported at Annex B of the delivery report.

47. Members queried the increase in non-directed altruistic liver lobe donations during 2017/18. Members also requested further information on long term clinical outcomes for donors, to inform the Authority’s consideration of the risk and consent issues surrounding organ donation.

48. The Chair asked the Executive to include an item on private patient transplant cases on the agenda of a future Authority meeting, to reflect the concerns raised in her introductory meetings with Authority Members.

49. The Authority noted the content of this paper.

Action 4: SMT to include the insights and learning arising from HTA Reportable incidents (HTARIs) in the post-mortem sector within the annual patient safety report that is due to be presented to members at the HTA Authority meeting, on 19 July 2018.

Action 5: Members to receive further information on the long
term clinical outcomes for donors, to inform the Authority's consideration of the risk and consent issues surrounding organ donation.

Action 6: The Executive to include an item on private patient transplant cases on the agenda of a future Authority meeting

Item 9 Development Report – Quarter Four – HTA (15/18)

50. Dr. Hazel Lofty presented this item and introduced the report.

51. Members were reminded that the Regulations to implement the EU Coding and Import Directives came into force on 1 April 2018. The Authority reiterated its gratitude to the HTA's Regulatory Development and Human Application Teams for successfully implementing these Directives.

52. The Authority was informed that progress on the licensed establishment engagement programme of work remained steady, with good progress made on the alpha-testing phase of the online forum. The project team had also been engaged on discussions around preparations to enable the HTA to comply with the General Data Protection Regulation (GDPR) as it applies to stakeholder engagement.

53. The Authority was also informed that, despite a number of resource constraints, steady progress has been made on other development areas during quarter four. This included progress on the enquiries project and development of horizon scanning. The Executive had also carried out a more detailed analysis of the HTA's findings in the post-mortem sector. This work had been triggered by the increase in non-compliance observed during the first two quarters of 2017/18.

54. Members were advised that data from the 2017/18 business year had now been collected and was being analysed to inform a report to the Authority on the outcomes of the HTA’s regulation and their impact on patient safety and public confidence. Dr Hazel Lofty said that this had involved the manual collation of data and that the Executive would be reviewing the better use of the HTA’s systems to compile future reports.

55. Members were informed that the project to explore the
opportunities available to strengthen or formalise the current Independent Assessor (IA) framework remained ongoing. Members were also advised that an additional 19 IAs had been trained during quarter four and that this had increased the number of IAs to 122. Members asked the Executive to ensure that the project would consider measures to improve the effectiveness and profile of IAs as well as increasing the number of available assessors.

56. The Authority was advised that a project to review and improve the induction of Regulation Managers was currently underway. Dr. Hazel Lofty assured Members that the Executive was confident that some of the improvements arising from this project would be in place for the three Regulation Managers that were due to join the HTA during May and June.

57. Members asked whether there was scope for the alignment of training aimed at licensed establishments with the HTA’s business plan. Members also queried the possibility of the HTA working in collaboration with other training providers and the scope to recoup external training costs through charging.

58. Dr. Hazel Lofty advised that feedback from external stakeholders indicated an ongoing appetite for the HTA to provide training to external users. Members were also informed that, in addition to ongoing improvements to online resources, further consideration would also be given to the production of sustainable training options for those working at licensed establishments.

59. Dr. Stuart Dollow noted the HTA Executive’s commitment to develop proposals for a strategy to address the potential risks across multiple establishments arising from Third Party Agreements in the Human Application sector.

60. The Authority noted the content of this paper.

<table>
<thead>
<tr>
<th>Item 10</th>
<th>Deployment Report – Quarter Four – HTA (15/18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>61.</td>
<td>Richard Sydee presented this item and introduced the report.</td>
</tr>
<tr>
<td>62.</td>
<td>Richard Sydee informed the Authority that the 2017/18 financial year had concluded with a surplus of £77k. Members were advised that the provisional figures within the report had yet to</td>
</tr>
</tbody>
</table>
be signed off by auditors. The Authority was informed that the surplus was largely due to the cumulative effect of staff vacancies throughout the year. It was argued however, that the additional controls that were implemented mid-year to control expenditure remained justified given the status of the budget at the start of the financial year.

63. Richard Sydee said that income for the year had exceeded budget by £68k. This was due to increases in ‘Other income’ which included rent, recharges for seconded staff and income from the devolved governments.

64. Members were advised that the increase in the other income stream had been offset by shortfalls from licensing and application fees due to the ongoing contraction of activities across all six sectors.

65. Richard Sydee said that overall expenditure was £27k below the 2017/18 budget. This position had been impacted by the inclusion of a provision for the increase in other HTA’s rent and the associated VAT relating to both 2016/17 and 2017/18 financial years. Members were informed that the SMT had taken the decision to provide for this charge as Department of Health and Social Care Estates have failed to reach agreement with all of the ALBs affected.

66. Members noted that the training budget was underspent, due to the limited uptake of training by staff. Members also noted the Executive’s concern that this underspend could also have been due to increased workloads in some areas of the business.

67. Members commended the efforts of the Resources Directorate and diligence of HTA Staff in delivering an effective budget during a challenging financial year.

68. The Authority noted the content of this paper, pending a minor amendment to the table under paragraph 21 and reinstatement of the missing table under paragraph 35 of the report.

Action 7: Richard Sydee to amend the table under paragraph 21 and reinstate the missing table under paragraph 35 of the Deployment report.
### Item 11  White space for non-agenda items – Oral

69. There was a round table discussion on the reporting of HTARIs.

70. Members were advised that the reporting of HTARIs in the PM sector was not a statutory requirement for licensed establishments. The requirement to report an HTARI was not mandated under HTA directions but instead is a condition of HTA licences which require licenceholders to provide information upon request, and it forms part of the HTA’s standards. Members were also informed that the current list of HTARI categories was established by an HTA project team in consultation with stakeholders but is regularly reviewed to address emerging trends.

71. Members discussed the relatively low number of incidents and reach of HTARI reporting in the context of the total number of mortuaries that are licensed by the HTA and the annual number of post mortem examinations that are conducted in those establishments. Members queried the potential scale of non/under-reporting by establishments. Members were advised that HTARI reporting is scrutinised on inspection although this issue would be kept under review.

72. Members also queried how the cumulative data derived from HTARIs was used. Members were informed that HTARI data was used by the HTA as a mechanism to respond to incidents occurring within establishments and as an indicative indicator of potential issues to be explored with licensed establishments. The requirement for Corrective and Preventative Action reports to address HTARIs was determined by the approach adopted by respective establishments in response to incidents.

### Item 12  Audit and Risk Assurance Committee update – Oral

73. Amanda Gibbon provided the Authority with an update on the HTA’s preparations to comply with the General Data Protection Regulation (GDPR). Members were reminded that the GDPR was due to come into effect on 25 May 2018.

74. Members were informed that in November 2017 the Audit and Risk Assurance Committee (ARAC) had received an Internal
Auditor report identifying a number of gaps in the HTA’s preparedness for the GDPR. The HTA had since formed a joint project team with the Human Fertilisation and Embryology Authority (HFEA) to oversee both organisations’ work to achieve compliance.

75. The Authority was advised that the ARAC had since received two reports from the Director of Resources, and was assured that the HTA was making good progress towards achieving a defensible position in time for the implementation of the regulation. Members were informed that the HTA anticipated that it would be fully compliant with the regulation by November 2018.

76. The Authority noted that, under the regulation, the current deadline for subject access requests would be reduced from 40 to 20 working days. Responding to members of the public within the new timescale was not expected to pose an issue for the HTA. Responding to any such requests from members of staff would, however, be more challenging due to limitations in the current HTA human resource records management system.

77. Members noted the progress made by the HTA towards meeting the new regulation and expressed their appreciation for the work undertaken by the Resources Directorate on this issue.

<table>
<thead>
<tr>
<th>Item 13</th>
<th>Stakeholder and Fees Group meeting update – Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>78.</td>
<td>Bill Horne outlined the matters of interest arising from the Stakeholders and Fees Group Meeting held on 9 May 2018.</td>
</tr>
</tbody>
</table>

79. Members were advised that ten stakeholders had attended the meeting and that all of the attendees had fully engaged in the discussions. Bill Horne said that, notwithstanding the good attendance at the meeting, he had asked staff at the HTA to review the current membership of the group to address gaps in representation of the HTA’s stakeholders.

80. Bill Horne informed the meeting that the group had received reports on better regulation and inspection reports, the codes and standards project implementation review and how we approached the intended publication of information on cryopreservation.
<table>
<thead>
<tr>
<th>Item 14</th>
<th>Update on opt-out for organ donation– HTA (17/18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>81.</td>
<td>The Authority noted the matters of interest arising from the meeting of the Stakeholder and Fees Group.</td>
</tr>
<tr>
<td>82.</td>
<td>Jessica Porter provided Members with an update on the progress and next steps regarding the DHSC opt-out proposals for deceased organ donation in England. Members were asked to note the content of the paper, and were invited to comment on the issues highlighted within it for consideration.</td>
</tr>
<tr>
<td>83.</td>
<td>The paper followed a previous item at the HTA Authority meeting on 8 February 2018, at which, Members were invited to comment on the draft HTA response to the Department’s public consultation on this issue. Members were reminded that their comments had been taken on board and that a further draft had been circulated to them via email correspondence. Additional amendments were also made prior to submission of the final response to the DHSC.</td>
</tr>
<tr>
<td>84.</td>
<td>Members were advised that by the end of the consultation period on 6 March over seventeen thousand responses had been received and that the DHSC was now in the process of analysing the responses in order to issue its response. Jessica Porter advised that the Government intended to publish its response in July.</td>
</tr>
<tr>
<td>85.</td>
<td>Members were therefore invited to give further consideration to the implications of the Bill as currently drafted, in particular:</td>
</tr>
<tr>
<td></td>
<td>• the timetable and resources required to produce a new Code of Practice, provide further required guidance and amend the remaining Codes;</td>
</tr>
<tr>
<td></td>
<td>• drawing on the HTA’s experience of regulating in both the organ donation and transplantation and human application sectors, and learning from implementing the Welsh legislation, what risks may be presented that could be addressed by including additional safeguards / policy intentions in the legislation;</td>
</tr>
<tr>
<td></td>
<td>• the practical implications of superintending compliance; and</td>
</tr>
<tr>
<td></td>
<td>• ongoing resources required and costs of implementing the new legislation.</td>
</tr>
</tbody>
</table>
86. The Authority discussed the prospective inter-border implications of implementing different consent legislation in England, Scotland, Northern Ireland and Wales. Members also considered the feasibility and scope of the HTA highlighting the possible risks of potentially differing requirements of the legislation emerging across the UK.

87. Members noted the content of the paper.

**Action 8: The Chair and Dr Hazel Lofty agreed to consider the HTA’s approach to highlighting the possible risks associated with differing consent requirements of any forthcoming organ donation legislation across the UK.**

<table>
<thead>
<tr>
<th>Item 15</th>
<th>Update on coding and import implementation – HTA (18/18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>88. Dr. Amy Thomas presented this item.</td>
<td></td>
</tr>
<tr>
<td>89. The Authority was reminded that the Regulations to implement the European Union (EU) Coding and Import Directives came into force on 1 April 2018. Members were informed that during quarter four, resources from the HTA Development and Human Application teams had been heavily focussed on implementing the requirements of these directives.</td>
<td></td>
</tr>
<tr>
<td>90. Dr. Amy Thomas also advised that, in consultation with stakeholders, the HTA had developed positions of interpretation, regulatory requirements and subsector specific guidance with respect to both coding and import. These had all been based on EU Directive and UK legislative requirements.</td>
<td></td>
</tr>
<tr>
<td>91. Members were informed that due to the tight timeframe involved, this had necessitated a risk-based approach, with updated import licences issued with Corrective and Preventative Action (CAPA) plans for the majority of importing establishments. The Authority was asked to note the limited amount of residual development activity that was set out within the paper and were given assurance that this would be completed in quarter one of the current business year.</td>
<td></td>
</tr>
<tr>
<td>92. As part of implementation process, all establishments in the HA sector were issued with a notice of proposal to vary the standard conditions of their licence. This licence variation was made to account for changes brought about by the amendment</td>
<td></td>
</tr>
</tbody>
</table>
regulations and was as follows:

a. a standard condition was modified to account for the authorisation of licensable activities on a ‘per tissue type’ basis and the publication of these authorisations in the EU Tissue Establishment Compendium;

b. two standard conditions were consolidated and updated to refer to current Directions (002/2018, described below); and

c. a standard condition was added to set out that importing establishments may only carry out the import of cells from outside of the EEA and Gibraltar under the terms specified in an Importing Tissue Establishment Licence Certificate (ITELC).

93. Members were advised that both Directives had resulted in more prescriptive licensing requirements. This meant that all changes to tissue types, or to the scope of import would need to undergo a standardised licence variation process, which was currently being established. This would provide a consistent process for triggering the update of licensing paperwork and establishment records within the HTA customer relationship management system.

94. Most establishments were issued with a fixed-term ITELC subject to completion of a CAPA plan. Establishments have up to three months to complete their CAPAs, at which point a continuous ITELC would be issued.

95. Members were informed that the assessment of CAPA information and reissue of ITELC would require input from RMs as well as the Regulatory Operations Team. This would need to be completed by 1 August 2018 to ensure that all ITELCs continue to have effect beyond that date.

96. Members noted the contents of this paper.

<table>
<thead>
<tr>
<th>Item 16</th>
<th>Any Other Business – Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>97.</td>
<td>The Authority agreed to consider proposals for future training items via email correspondence. It was agreed that Dr. Hazel Lofty would circulate the current list of proposed training topics</td>
</tr>
</tbody>
</table>
98. The Chair asked Members to raise any other business.

99. No further business was raised.

**Action 9:** Dr. Hazel Lofty to circulate the list of proposed training topics to members. Members to provide comments and any further suggestions, via return email to Dr Hazel Lofty.

The meeting closed at 14:29
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 5 May and the end of June 2018, which are not reported elsewhere.

Decision-making to date

2. This report was approved by the CEO on 12 July 2018 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 July 2018. In its July assessment, SMT noted evidence of a tightening labour market, making it increasingly difficult to recruit high-calibre staff directly, and the growing need to use recruitment agencies (with the associated costs). The announcement of the pay award restrictions also poses a risk to staff satisfaction. The continued uncertainty around the UK’s exit from the European Union and the final shape of any opt out legislation for organ donation are also being monitored closely for their potential impact on strategic risk.
Other issues

Organ Donation (Deemed Consent) Bill

5. As reported at the last meeting, the Organ Donation (Deemed Consent) Bill had its second reading debate on Friday 23 February 2018. The Bill has now been committed to a Public Bill Committee, but no date has yet been set for the Committee stage. The Public Bill Committee will scrutinise the Bill line by line.

6. The HTA continues to work closely with the Department for Health and Social Care on the likely progress of the Bill, and has begun to plan, at a high level, for the project that would be required to produce and consult on a Code of Practice to provide practical advice on any new legal requirements.

7. The Bill, as drafted, leaves a number of significant policy issues to be resolved. In line with our consultation response, we will press for these matters to be clarified in law to provide the clinical community with certainty and to allow the HTA to produce an authoritative Code of Practice.

Human Tissue (Authorisation) (Scotland) Bill

8. This Scottish Government Bill was introduced by the Cabinet Secretary for Health and Sport, Shona Robison MSP, on 8 June 2018.

9. The Bill’s purpose is to introduce a soft opt-out system of organ and tissue donation for the purposes of transplantation. It amends the Human Tissue (Scotland) Act 2006 to add to existing provisions in that Act, which provide for authorisation of removal and use of parts of the body of a deceased person for the purposes of transplantation and other specified purposes (e.g. research, education, training and audit).

10. It introduces the concept of deemed authorisation for deceased organ and tissue donation which will apply to most adults. This means that where a potential adult donor has not expressed any objections to donation for the purpose of transplantation, the adult’s authorisation may in some circumstances be deemed to have been given and the donation could proceed.

11. The HTA has no responsibilities under the Human Tissue (Scotland) Act, so this update is provided for information only.
Preparations for the UK’s Exit from the European Union

12. The HTA is a designated Competent Authority for two separate areas of EU legislation – the European Union Tissues and Cells Directives (EUTCD) and the European Union Organ Donation Directive (EUODD).

13. The HTA’s current regulatory frameworks for both sets of legislation are well established and set high standards of quality and safety for donors and patients in the UK. The Government’s priority is to maintain the same high standards for quality and safety after the UK exits from the EU.

14. Planning is ongoing so the Government can make the necessary changes to national regulations to maintain day one operability for the import and export of organs, tissues and cells under any EU exit scenario. The HTA is working closely with the Department for Health and Social Care in this area and has recently begun attending meetings of the DHSC EU Exit Operational Readiness Board.

Real Bodies Exhibition at NEC Birmingham

15. At the start of June, the HTA undertook a site visit inspection at the Birmingham NEC where it assessed and approved a licence for the public display of plastinated whole bodies.

16. The Human Tissue Act requires that the public display of human bodies of English, Welsh or Northern Irish provenance is lawful where there is appropriate consent. In the case of public display of a whole body, appropriate consent must be the written consent of the individual in life. However, the HT Act specifically excludes imported bodies from the requirement of appropriate consent for public display.

17. This distinction between the requirements for domestic and imported bodies, represents a new example of a potential cause of the strategic risk 3 – Failure to manage expectations of regulation, and has been added to the strategic risk register.

Competent Authority Meetings

18. The Competent Authority (CA) meeting for Tissues and Cells was held on the 20 and 21 June 2018. An update was provided on the Commission’s ongoing review of the EU Tissues and Cells Directive. This is the first formal evaluation of this legislation since its adoption in 2004. Although the formal deadlines for submissions have now passed, the Commission are still accepting input into the consultation. Member States (MSs) were encouraged to review the published consultation responses to understand stakeholder concerns regarding the legislation.
19. Status updates were also given on a range of EU funded projects including GAPP and VISTART, to which the HTA is currently contributing. The former project aims to facilitate the development of a common and optimal approach to assess and authorize preparation processes in blood and tissues establishments. The latter project aims to promote and facilitate harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells and to increase inter-MS collaboration and confidence in each other’s inspection and vigilance programmes.

20. A topic of discussion that ran throughout the meeting was the need for, and interest in, the setting up of an Inspector Expert subgroup similar to the Vigilance Expert subgroup that was established recently. No decisions were taken on this during the meeting, but the concept was generally well received and is to be formally considered as part of the VISTART and GAPP projects.

21. The Competent Authority meeting for Organs was held on 27 and 28 June 2018 in Brussels. Jess Porter gave a presentation on the use of ex-vivo organ perfusion devices to understand the extent that these machines are being used in other Member States. This will be used to inform the approach we may take to regulation where this technology is used during the organ donation and transplantation process. Some policy work in this area will be undertaken during the next three months.

22. Other key issues on the agenda included updates on EU funded research projects and forthcoming activities for the Council of Europe and World Health Organisation.

Accountability to the Department of Health and Social Care

23. The HTA is scheduled to meet with DHSC on 17 July 2018 as part of its regular quarterly accountability meetings. An oral report of the key issues discussed will be provided at the Authority meeting.

Estates Management

24. The Executive continues to engage external stakeholders on possible locations for the HTA’s headquarters when the current lease for 151 Buckingham Palace Road ends in 2021.

25. At a meeting on 14 June, SMT agreed a set of working assumptions about what the HTA should be trying to achieve from its future estates strategy. These assumptions will form a basis for the assessment of options as they emerge. The assumptions, in outline, are that we will:

   a. seek a continued physical presence/headquarters in London;
   b. seek reliable access to meeting space that will reflect a greater need for all staff meetings and Authority meetings that allow Members and staff to interact;
c. aim to configure the space around the work that needs to be undertaken by staff who cannot work remotely

d. look at the options for hubs or touchdown points in other government buildings for any staff that are recruited under the expectation of remote working;

e. aim to achieve government benchmark targets for desk ratios.

26. We have provided staff with an overview of the key issues and likely location options and will continue to engage with them as the picture becomes clearer. We would anticipate bringing high-level business cases for different options to the Authority’s strategy away day in September.

All staff meeting 21 May

27. An all staff meeting took place off site on 21 May. The agenda included presentations from each part of the business to celebrate successes from the last business year. We also presented the business priorities and key projects that we will be taking forward in 2018/19. The CEO provided feedback to staff on the themes to emerge from his all staff 1-2-1 meetings (which were reported to the Authority at its May meeting). The Head of Business Technology ran an awareness-raising session on the key requirements stemming from the General Data Protection Regulation.

28. We also ran two interactive table discussions. The first sought staff views on developing our People and Business Technology Strategies. The second sought staff views on adapting our regulatory approach to achieve more timely compliance with HTA requirements, in particular with respect to post-inspection processes.

Authority Strategic Planning Away Day September 2018

29. Plans are underway for the Authority’s annual Strategic Planning Away Day to be held on 25 September 2018 at etc. Venues in Pimlico.

30. In outline, we propose the Authority should use this year’s session to:

a. consider any changes of strategic significance in the operating environment over the last twelve months;

b. reach a common view with the executive about what the outcomes and benefits that will be delivered by 2021 as part of the current strategy, in particular with respect to people and digital development;

c. assess the adequacy of the route map that the executive is currently producing as a basis for its detailed planning. The route map will set out the thinking on the key strands of activity to deliver outcomes and benefits and the likely timing of these.

d. set its preferred direction of travel for the estates strategy to 2021 in light of the emerging options;
e. assess the issues associated with funding the work required to deliver the vision of greater sustainability, agility and resilience by 2021; and  
f. identify emerging themes in the strategic risks faced by the HTA in light of its consideration of a-e.

31. At the last two away days, the role played by the external facilitator has proved quite limited. As a result, we do not intend to engage an external facilitator this year, and propose that the CEO chairs the session (as was the case last year). We will seek active involvement in the design of the day from Authority Members to ensure that the greatest possible time is available for discussion.

Complaints report

32. The HTA did not received any complaints in quarter one.
Overview: Risks reflect the strategy for 2018 - 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. HTA role in the production of Opt-out Code of Practice

Recruitment for Regulation Managers is ongoing, with a number of more recently recruited Regulation Managers now signed off and new starters in post; recruitment to key posts has now been completed. This will increasingly have a mitigating impact.

<table>
<thead>
<tr>
<th>Risk</th>
<th>May 2018</th>
<th>June 2018</th>
<th>July 2018</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Failure to regulate appropriately (Risk to Delivery a-d &amp; f and Development a-d)</td>
<td></td>
<td></td>
<td></td>
<td>A good regulatory framework and processes are in place and continuous improvement is planned. It is important to identify changes and remain agile to adapt to these. A number of new regulation managers have increased the organisation’s capability and strengthened our regulatory regime and a recent recruitment has resulted in two new starters and further offers. Recruitment for other vacancies is ongoing - although we are seeing high levels of candidates drop out at interview stage. The development of a revised induction programme for RMs and a review of Standard Operating Procedures is required in order to achieve our aims of recruiting and training RMs more effectively and this is underway.</td>
</tr>
<tr>
<td>2. Failure to manage an incident (Delivery, Development and Deployment)</td>
<td></td>
<td></td>
<td></td>
<td>Plans are in place to manage an incident. These plans are complete and were tested during Q4 of 2017/18. The CIP was utilised to manage a building power outage during March 2018 and a regulatory issue in April 2018. Lessons learnt papers were discussed at ARAC, but the incidents were managed well.</td>
</tr>
<tr>
<td>3. Failure to manage expectations of regulation (Risk to Delivery e and Development c)</td>
<td></td>
<td></td>
<td></td>
<td>We continue to communicate our remit and advise where appropriate. There is ongoing dialogue with DH and stakeholders about emerging issues and we provide clear lines to the media when necessary. Communicating on an issue which is not within remit but appears to the public as if it should be is challenging. The number of perimeter issues shows no sign of decreasing, a recent regulatory issue highlighting the limitations of our legislation as well as uncertainty relating to EU exit will continue to occupy regulatory resources. The regulations on Import and Coding have now passed into law. Although complete for 31 March 2018 there will be residual work to pick up in 2019/20. Risk direction changed to focus on perimeter issues and longer term uncertainty to change in the overall score rating.</td>
</tr>
<tr>
<td>4. Failure to utilise our capabilities effectively (Delivery a-e) (Development a, c and d)</td>
<td></td>
<td></td>
<td></td>
<td>We continue to be in a position to use the skills of our newer recruits more fully. Wider utilisation and pressure continue to be monitored closely by the management team and the actions agreed as a result of the staff survey are now being implemented. We have achieved our planned position relating to GDPR by the 25 May 2018 implementation date, we have an initial defensible position and a plan for achieving full compliance for any outstanding areas by November 2018.</td>
</tr>
<tr>
<td>5. Insufficient, or ineffective management of financial resources (Deployment b)</td>
<td></td>
<td></td>
<td></td>
<td>We begin the 2018/19 financial year with a broadly balanced budget. Although we have seen a small decline in licence numbers, a comprehensive plan has been conducted and we will continue to monitor debtor levels and for any further changes to licence numbers.</td>
</tr>
</tbody>
</table>

Risks are assessed by using the grid below

<table>
<thead>
<tr>
<th>Risk</th>
<th>Impact</th>
<th>Likelihood</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Rare</td>
<td>1% - 3%</td>
<td>Very Low</td>
<td>1</td>
</tr>
<tr>
<td>2. Unlikely</td>
<td>3% - 9%</td>
<td>Low</td>
<td>2</td>
</tr>
<tr>
<td>3. Possible</td>
<td>11% - 33%</td>
<td>Medium</td>
<td>3</td>
</tr>
<tr>
<td>4. Likely</td>
<td>34% - 67%</td>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>5. Almost Certain</td>
<td>68% - 100%</td>
<td>Very High</td>
<td>5</td>
</tr>
</tbody>
</table>

Risk scoring matrix

<table>
<thead>
<tr>
<th>Impact</th>
<th>Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>Very Low</td>
<td>2</td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
</tr>
<tr>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>Very High</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Risk Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Low</td>
<td>1</td>
</tr>
<tr>
<td>Low</td>
<td>2</td>
</tr>
<tr>
<td>Medium</td>
<td>3</td>
</tr>
<tr>
<td>High</td>
<td>4</td>
</tr>
<tr>
<td>Very High</td>
<td>5</td>
</tr>
</tbody>
</table>

Risk Score = Impact x Likelihood
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK/PRIORITY</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROL/MECHANISMS</th>
<th>RESIDUAL RISK/PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Failure to regulate in a manner that maintains public safety and confidence and is appropriate (Risk to Delivery objectives a-d &amp; Development objectives adj)</td>
<td>Risk Owner: Allan Marriott-Smith</td>
<td>Cost</td>
<td>Ongoing</td>
<td>Regulatory model</td>
<td>Regulatory decision making framework</td>
<td>K Preventative</td>
<td>Authority developed and approved the HTA Strategic Business Plan 2018/19</td>
<td>K Preventative</td>
<td>Authority developed and approved the HTA Strategic Business Plan 2018/19</td>
<td>HTA Strategy published in April</td>
</tr>
</tbody>
</table>

**Causes:**
- Failure to identify regulatory non-compliance
- Regulation is not transparent, accountable, proportionate, consistent and targeted
- Regulation is not sufficiently agile to respond to changes in sectors
- Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, inadequate contingency planning, difficulty in recruiting, difficulty in retaining staff
- Inadequate adherence to agreed policies and procedures, in particular to relate to decision making
- Poor quality or out of date policies and procedures
- Failure to identify new and emerging issues within HTA remit
- Failure to properly account for Better Regulation
- Insufficient funding in regulated sectors
- Risk based approach to implementing Import and Coding regulations ahead of 31 March 2018 deadline

**Effects:**
- Loss of public confidence
- Compromises to patient safety
- Loss of impact from regulated sectors potentially losing its challenge to decisions and non-compliance
- Reputational damage
- Increases in the number of major and critical shortfalls

**Quality management systems**
- HTA quality management system contains decision making framework, policies and Standard Operating Procedures to achieve adherence to the regulatory model
- Individual staff Member responsible for QMS, automated review reminders, management oversight of progress on updates

**People**
- HTA People Strategy roadmap 2017/18
- Management information and assessment presented to the Authority quarterly as part of the Deployment Report

**Risk-based**
- Training and development of professional competence
- Recruitment policy
- Staffing levels and risks reported quarterly to the Authority

**Quality management systems**
- Internal audit of quality management system schedule as per membership of the Honda association (HCA) by March 2018

**Regulatory model**
- Delivery of Licensing and importation review projects to strengthen our regulatory strategy (HL) 2016/18
- Extension of reporting requirements to relevant sectors in the Research sector (CSO) Proposed in 2016/18
- Consideration of import licensed establishments in risk assessment planning, Establishments assessed in order of existing risks profile and level of activity

**People**
- HTA People Strategy roadmap 2017/18
- Internal audit of quality management system schedule as per membership of the Honda association (HCA) by March 2018

**Other**
- Strengthening horizon scanning arrangements
- Ongoing activity in the HTA Strategic Business Plan 2018/19

**Assurance over control and assured position**
- Assurance over control and assured position
- Assurance over control and assured position
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Inability to manage an incident impacting on the delivery of HTA strategic objectives. This might be an incident:</td>
<td>5 3</td>
<td>Future, should event occur</td>
<td>3 2</td>
<td>Critical incident response plan, SOPs and guidance in place, regularly reviewed, including by annual training, and communicated to staff</td>
<td>X X</td>
<td>Preventative</td>
<td>Monthly reports to HTAMG</td>
<td>Review from August 2017, reviewed by ARAC October 2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>relating to an activity we regulate (such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA)</td>
<td></td>
<td></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 enquires SOPs</td>
<td>X</td>
<td>Preventative</td>
<td>Policy reviewed annually, training specifications and notes after incident reviews</td>
<td>Media policy to be reviewed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>caused by deficiency in the HTA’s regulation or operation</td>
<td></td>
<td></td>
<td></td>
<td>Accessible lines to take and key messages for likely scenarios</td>
<td>X</td>
<td>Preventative</td>
<td>Documented, incidents reported to Chair and in Delivery Report</td>
<td>Delivery report to Authority meeting May 2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>where we need to regulate, such as with emergency mortuaries</td>
<td></td>
<td></td>
<td></td>
<td>Availability of legal advice</td>
<td>X</td>
<td>Preventative</td>
<td>Lawyers specified in Critical Incident Response Plan, SMT approval</td>
<td>In place</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>that causes business continuity issues (Risk to all Delivery Development and Deployment objectives)</td>
<td></td>
<td></td>
<td></td>
<td>Fit for purpose Police Referrals Policy</td>
<td>X</td>
<td>Preventative</td>
<td>Annual review of policy (minimum), usage recorded in SMT minutes</td>
<td>Policy reviewed February 2017 &amp; reviewed April 2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Risk owner: Chris Birkett</td>
<td></td>
<td></td>
<td></td>
<td>Onward delegation scheme and decision making framework agreed by the Authority</td>
<td>X X</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>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulatory decision making framework</td>
<td></td>
<td></td>
<td></td>
<td>IT security controls and information risk management</td>
<td>X X</td>
<td>Preventative</td>
<td>Reports to Authority of key decisions in Delivery Report</td>
<td>Satisfactory reports made in May 2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Business continuity plan regularly reviewed and tested</td>
<td></td>
<td></td>
<td></td>
<td>Evaluate test exercise of incident and feedback to all staff (SB) May 2017</td>
<td>X X</td>
<td>Preventative</td>
<td>Critical incident Response Plan and notes of test, reported to SMT</td>
<td>CIP was used to manage a power outage during March 2018 and a regulatory incident arising in March 2018</td>
<td></td>
<td></td>
</tr>
<tr>
<td>REF</td>
<td>RISK/RISK OWNER</td>
<td>CAUSE AND EFFECTS</td>
<td>INHERENT RISK PRIORITY</td>
<td>PROXIMITY</td>
<td>EXISTING CONTROL/MITIGATIONS</td>
<td>RESIDUAL RISK PRIORITY</td>
<td>ACTIONS TO IMPROVE MITIGATION</td>
<td>LINE OF DEFENCE</td>
<td>TYPE OF CONTROL</td>
<td>ASSURANCE OVER CONTROL</td>
<td>ASSURED POSITION</td>
</tr>
<tr>
<td>-----</td>
<td>----------------</td>
<td>-------------------</td>
<td>-----------------------</td>
<td>-----------</td>
<td>-----------------------------</td>
<td>-----------------------</td>
<td>------------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>-----------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>2</td>
<td>Failure to manage public and professional expectations of human tissue regulation in particular stemming from limitations in current legislation or implementation of HTA regulatory reach</td>
<td><strong>Risk Owner:</strong> Hazel Lofty</td>
<td><strong>Cause:</strong> External factors</td>
<td>4</td>
<td>Ongoing</td>
<td>4</td>
<td>Monitoring</td>
<td>Ongoing log</td>
<td>Log in place and reviewed at HTAMG quarterly. New issues identified in causes and effects</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Matters which certain stakeholder groups believe require review</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Scope of relevant materials e.g. waste products</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Licensing requirements e.g. transplantation research</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulation relating to child bone marrow donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Issues raised by emergence of social media e.g. non-related donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strengthening of civil sanctions for non-compliance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Matters which stakeholders/public may expect to be inside regulatory scope</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Efficacy of clinical treatment from banked tissue and treatments carried out in a single surgical procedure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Police notices</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Products of conception and fetal remains</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Data generated from human tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Failure directions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Forensic research facilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cryopreservation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Body stores / 'Taphonomy'</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Imported materials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inadequate stakeholder management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Effect</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diminished professional confidence in the adequacy of the legislation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reduced public confidence in regulation of matters relating to human tissue</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regulatory damage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**INHERENT RISK**

- No scheduled review of Human Tissue Act and associated regulations
- Rapidly advancing life sciences
- Potential move away from the UK as basis for some regulated establishments due to EU Exit and changes in exchange rates
- Proposed move to deemed consent for organ donation within England
- Uncertainty posed by EU Exit

**RESIDUAL RISK**

- Active management of issues raised by the media – including the development of the HTA position on issues
- Active management of issues raised by the media – including the development of the HTA position on issues
- Regular reporting to DH sponsorship
- Monitoring
- Stakeholder Group meeting minutes
- Authority minutes (including Public Authority Meeting)
- Last stakeholder group meeting in October 2017
- Public Authority meeting in June 2017

**CONTROL**

- Preventative/Detector
- Quarterly reports to Authority on communication (including media) activities
- Last report in September 2017 - satisfactory

**ASSURANCE**

- Duty and its use understood by SMT and Chair
- The duty has not been acted upon in the current business year

**ASSURED POSITION**

- Full year accountability meeting in May 2017. Positive. Last quarterly meeting April 2018.
- Monitoring Ongoing log
- 123
- Pregnancy remains guidance published
- Published guidance for particular issues (e.g. pregnancy remains and shortly, cord blood)
- Failure to manage issues (e.g. pregnancy remains, and shortly, cord blood)
- External factors
- • No scheduled review of Human Tissue Act and associated regulations
- • Rapidly advancing life sciences
- • Potential move away from the UK as basis for some regulated establishments due to EU Exit and changes in exchange rates
- • Proposed move to deemed consent for organ donation within England
- • Uncertainty posed by EU Exit

**PRIORITY LINE OF DEFENCE**

- Project management, monthly HTAMG updates, quarterly update in Delivery Report
- Delivered
- Planning for EU Exit:
- • Inadequate stakeholder engagement
- • Diminished professional confidence in the adequacy of the legislation
- • Reduced public confidence in regulation of matters relating to human tissue
- • Regulatory damage

<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK PRIORITY</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROL/MITIGATIONS</th>
<th>RESIDUAL RISK PRIORITY</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>RISK/RISK OWNER</td>
<td>CAUSE AND EFFECTS</td>
<td>INHERENT RISK PRIORITY</td>
<td>PROXIMITY</td>
<td>EXISTING CONTROL/S/MITIGATIONS</td>
<td>RESIDUAL RISK PRIORITY</td>
<td>ACTIONS TO IMPROVE MITIGATION</td>
<td>LINE OF DEFENCE</td>
<td>TYPE OF CONTROL</td>
<td>ASSURANCE OVER CONTROL</td>
<td>ASSURED POSITION</td>
</tr>
<tr>
<td>-----</td>
<td>-----------------</td>
<td>-------------------</td>
<td>----------------------</td>
<td>----------</td>
<td>-------------------------------</td>
<td>----------------------</td>
<td>---------------------------</td>
<td>----------------</td>
<td>----------------</td>
<td>---------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>4</td>
<td>All causes</td>
<td></td>
<td>People</td>
<td>4</td>
<td>People</td>
<td>3</td>
<td>QMS reminders as policies due for review.</td>
<td>Preventative/ Monitoring</td>
<td></td>
<td>Guidance issued April 2018</td>
<td>Regular review cycle will recommence in late summer</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Regularly reviewed set of people-related policies cover all dimensions of the employee lifecycle</td>
<td></td>
<td>Established annual Performance Development Planning (PDP) process supported by mandated in year processes (1-2-1s and mid year review)</td>
<td>Preventative/ Monitoring</td>
<td></td>
<td>PDP guidance reviewed annually and approved by SMT. newly introduced countersigning officer check</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Standard objectives for all line managers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Regular review of HTA organisational structure and job descriptions</td>
<td></td>
<td>Regular review of HTA organisational structure and job descriptions</td>
<td>Preventative</td>
<td></td>
<td>Staff survey, and interviews, staff forum (attended by SMT Member and Head of HR)</td>
<td>Report of exit interview presented to Authority in September 2017 (Staff Survey action plan in place March 2016) ARAC chair regularly discusses staff issues with chair of staff forum.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td>Monitoring/ Detective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Data relating to establishments securely stored with the Customer Relationship Management System (CRM)</td>
<td>Preventative/ Monitoring</td>
<td></td>
<td>Upgrades to CRM, closely managed changes to CRM development, internal audit of personal data security.</td>
<td>CRM upgrade roll out to be scheduled following completion of UAT</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Staff training in key business systems</td>
<td>Preventative</td>
<td></td>
<td>Systems training forms part of the induction process for new starters</td>
<td>Ongoing records of all new starters trained in key business systems</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>IT systems protected and assurances received from 3rd party suppliers that protection is up to date</td>
<td>Preventative/ Monitoring</td>
<td></td>
<td>Quarterly assurance reports from suppliers. Monthly operational cyber risk assessments.</td>
<td>Annual SIRO report presented to ARAC June 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td>Monitoring/ Detective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td>Monitoring/ Detective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td>Monitoring/ Detective</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Feedback from HTA people about work, management and leadership</td>
<td>Monitoring/ Detective</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Failure to utilise people, data and business technology capabilities effectively |

**Risk Owner:** Allan Marriott-Smith

**Type of Control:** Preventative/ Monitoring

**Assurance Over Control:** Regular review cycle will recommence in late summer
<table>
<thead>
<tr>
<th>REF</th>
<th>RISK/RISK OWNER</th>
<th>CAUSE AND EFFECTS</th>
<th>INHERENT RISK</th>
<th>PROXIMITY</th>
<th>EXISTING CONTROLS/MITIGATIONS</th>
<th>RESIDUAL RISK</th>
<th>ACTIONS TO IMPROVE MITIGATION</th>
<th>LINE OF DEFENCE</th>
<th>TYPE OF CONTROL</th>
<th>ASSURANCE OVER CONTROL</th>
<th>ASSURED POSITION</th>
</tr>
</thead>
</table>
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | 3 | Monitoring | X | Preventative | Financial projections, cash flow forecasting and monitoring | Monitoring Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH | Update agreed by the Authority November 2017 | Preventative Monthly finance reports to SMT and quarterly to Authority | Last quarterly report March 2018 |
|     |                  |                  |              |          |                             |              |                             | All            |                | Budgetary control policy reviewed annually and agreed by SMT |                |
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | Licence fee modelling | X | Preventative | Rigorous debt recovery procedure | Preventative | Monitoring | Reserves policy reviewed annually and agreed by ARAC | Last agreed February 2017 |
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | Reserves policy and levels reserves | X | Monitoring | Delegation letters set out responsibilities | Preventative | Monitoring | Delegation letters issued annually | Issued in April 2018 |
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | Prioritisation when work requirements change | X | Preventative | Fees model provides cost/income information for planning | Preventative | Monitoring | Annual review of fees model, reported to SMT and Authority | Last HTAMG report April 2018 |
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | Annual external audit | X | Detective | Monitoring of income and expenditure (RS) | Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH | NAO report annually | Monitoring | Monthly finance reports to SMT and quarterly to Authority, Quarterly reports to DH | Last quarterly report March 2018 |
| 5   | Insufficient, or ineffective management of financial resources | • Fee payers unable to pay licence fees  
• The number of licensed 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 | Horizon scanning for changes to DH Grant-in-aid levels and arrangements (RS) | X | Detective | Monitoring of income and expenditure (RS) | Quarterly Finance Directors and Accountability meetings | Last FDs meeting Nov 2017 | Monitoring | Monitoring | Last report in June 2017 - clear opinion |

**Risk to Deployment objective b:**

**Risk Owner:** Richard Sydee
## Authority Report
### Delivery – Quarter One 2018/19

<table>
<thead>
<tr>
<th>Date</th>
<th>19 July 2018</th>
<th>Paper Reference</th>
<th>HTA (21/18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>7</td>
<td>Author</td>
<td>Christopher Birkett/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 program 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)
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 20a/18 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was approved by the CEO on 12 July 2018 for submission to the Authority.

Action required

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

Directors’ summary

5. During Quarter One of the 2018-19 business year, we returned to a more typical inspection schedule and had a more stable period in terms of responsive regulatory activities.

6. One critical shortfall was reported during the period, which is referred to below.

Critical shortfalls

7. There was one critical shortfall reported during Quarter One. The shortfall was categorised as a critical due to cumulative related findings arising from a routine inspection of a Human Application sector establishment. The shortfall related to use of expired tissues and cells products for patient treatment, and conflicting procedural documents relating to storage of tissues and cells.

Investigations

New investigations

8. There have been no new investigations in Quarter One.
Update on investigation reported in previous Delivery report (HTA 14/18)

Investigation 02/18

9. The HTA is continuing to work with the Administrators for the two establishments to ensure that samples and associated records are stored safely for the long term.

Non-routine site visit inspections

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

Police referrals

11. This section 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 01/18

12. This case related to unauthorised storage of tissues and cell products for Human Application.

13. SMT carefully considered the factors in favour of and against police referral. These were:
   a. Factors in favour of referral
      i. The alleged offence has the potential to damage public confidence in the use of human tissue.
      ii. The alleged offence poses a risk to public safety.
      iii. The alleged offence continued over a significant period of time.
   b. Factors against referral
      i. The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment.
      ii. A person committing the alleged offence concerned acknowledged the breach of human tissue legislation to the Authority and/or the person concerned has not attempted to conceal the matter.
iii. It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding.
iv. The alleged offence has limited potential to damage public confidence in the use of human tissue.

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

_Police referral 02/18_

15. This case related to an establishment removing material from the deceased without appropriate consent.

   a. Factors in favour of referral
      i. The information indicating the alleged offence is assessed to be reliable

   b. Factors against referral
      i. The alleged offence poses no risk to public safety
      ii. The alleged offence has limited potential to damage public confidence in the use of human tissue
      iii. A person committing the alleged offence concerned acknowledged the breach of human tissue legislation to the Authority and/or the person concerned has not attempted to conceal the matter
      iv. The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment

16. On balance, SMT agreed with the recommendation that the factors against referral outweighed those in favour and decided not to refer the matter to the police.

_Police referral 03/18_

17. This case related to an establishment carrying out processing activities without being licensed for this activity. The establishment holds an HTA licence for the activities of distribution, procurement, storage and testing under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). However this licence does not cover processing activities.

   a. Factors in favour of referral
      i. The alleged offence poses a risk to public safety
ii. The information indicating the alleged offence is assessed to be reliable

b. Factors against referral
   i. The alleged offence has limited potential to damage public confidence in the use of human tissue
   ii. A person committing the alleged offence concerned acknowledged the breach of human tissue legislation to the Authority and/or the person concerned has not attempted to conceal the matter
   iii. The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment
   iv. It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding

18. On balance, SMT agreed with the recommendation that the factors against referral outweighed those in favour and decided not to refer the matter to the police.

Police referral 04/18

19. Legal advice regarding Regulation 14 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 had been received, which confirmed that disclosure of certain information by a former employee of a HTA-licensed establishment to a journalist would constitute an offence and that SMT would take a decision on whether we should refer the case to the police.

20. SMT considered the factors for against police referral within the policy. These were:

   a. Factors in favour of referral
      i. The alleged offence has the potential to damage public confidence in the use of human tissue
      ii. The information indicating the alleged offence is assessed to be reliable.

   b. Factors against referral
      i. The alleged offence poses no risk to public safety.
      ii. The alleged offence has limited potential to damage public confidence in the use of human tissue.
      iii. The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory actions or changes in the governance arrangements at the establishment.
iv. It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding.

21. SMT agreed that the factors against referral outweighed the factors in favour of referral in this instance. A decision was taken that we should inform the clients of the legal situation, and that our decision does not prevent them taking further action independently should they wish to do so.

Legal notices

22. We did not issue any Directions in Quarter One.

Regulatory decision meetings

23. Two regulatory decision meetings (RDMs) were held in Quarter One:

24. RDM One: potential storage of tissue without appropriate licensing or exemption
Information about potential unlicensed storage came to light during a licence application assessment. The establishment has since been assessed, visited and granted a HTA licence. The historical breach will be considered by SMT for a decision on potential police referral.

25. RDM Two: significant shortfalls identified during inspection
A large number of shortfalls were identified during a routine inspection at an establishment in the post mortem sector. An RDM meeting was held to discuss the findings, agree the level of shortfalls and plan the appropriate regulatory approach.

Reconsiderations, representations and appeals

26. No reconsiderations, representations or appeals were considered during Quarter One.

Other regulatory activity

27. There was one CAPA follow-up visit in Quarter One.

28. The visit was undertaken for an establishment in the Human Application sector where a number of shortfalls had been identified at a previous inspection, and it was felt that progress would be best assessed on-site and in-person. The HTA team was able to discuss actions with the DI, close some CAPAs and give further advice on how to progress remaining actions.
Enquiries

General enquiries

29. During quarter one, we received 697 general enquiries, compared to 1,054 in the previous quarter. The enquiries included:

   a. 260 from members of the public about body donation (145 were received via email or phone, and in the post, and 115 via the website). This compares to 535 in the previous quarter.
   b. 437 from professionals about licensing or other areas of our regulatory work, compared with 308 in the previous quarter.

30. Of these enquiries, 284 were received via the website, compared to 574 in last quarter. Other enquiries are usually received by phone.

31. 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 one, 96 percent were closed in our case management system within ten working days\(^1\), 95 percent in the previous quarter. Over quarter one, 99.5% percent of enquiries were responded to within twenty working days, with the average time taken in quarter one standing at four days. The cases that fell outside ten working days generally involve concerns raised with us about establishments, or more complex regulatory matters.

Freedom of Information Act (FOIA) requests

32. We received eight requests for information under the Freedom of Information Act 2000, during quarter one. The number of requests received during the quarter remains broadly consistent with the volume of requests that were received previously. We publish all FOIA responses on our website.

Stakeholder engagement

Coding and import Directives

33. The coding and import Directives were transposed into UK law via the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 on 1 April.

34. On the 1 April, we published an updated version of the HTA’s Guide to Quality and Safety Assurance for Tissues and Cells for Patient Treatment (the Guide) on the

\(^1\) The 96% figure is indicative, as ten working days need to have elapsed to give the true figure for the enquiries KPI in June
website and via email to all establishments in the HA sector. The Guide was brought into effect via a new set of Directions 002/2018 which revoked and replaced Directions 003/2010. These were also published on the website and shared via email.

35. Establishments were also issued with updated standard conditions which applied to their licence from 1 April. These now reflect updated HTA Directions, but also set out the circumstances under which the HTA must be notified of changes to licensable activities and the tissue types that an establishment is authorised to work with.

36. We will continue to communicate with establishments to fully implement and embed the requirements as we begin to inspect against them.

Results from the public evaluation

37. In May, we published the full report and findings from our public evaluation work on the website and via the professional newsletter.

38. The results of the evaluation will help us understand what the public know, think, and expect of the HTA, in order to inform our ongoing public engagement work.

Information for the public on the cryogenic freezing of a human body

39. Following a review of the prevalence and potential risk to the public of services offering the cryopreservation of a whole body or body parts, the HTA has created a short piece of guidance for the public to provide independent advice about the practice.

40. The guidance is in the final stages, having been reviewed by the HTA Public Panel, whose feedback was taken into consideration.

41. The guidance was also discussed at the May Stakeholder Group Meeting and feedback from Members has been taken into account.

42. Once it has been through internal governance channels we expect it to be made available on our website from quarter two of the 2018-19 business year.

HTA establishment button

43. The HTA continues to promote the use of the ‘establishment button’ via the professional newsletter and social media.

44. Members will recall that the button is an HTA branded digital feature that establishments can use on their website to indicate that they are licensed by us. The HTA does not
allow other organisations to use its logo for marketing and advertising purposes, so this button provides establishments with an opportunity to show they are licensed and regulated by the HTA. The button also links back to that establishment’s licence page on the HTA website.

45. There are currently 41 buttons active on establishment websites. We have also included information on the use button in our updated logo and branding policy and our licensing correspondence.

Joint Health Research Authority / HTA public dialogue work

46. We have collaborated with the HRA on a public dialogue project, which has been part-funded by Sciencewise (part of BEIS), and commissioned with Ipsos MORI.

47. The project aims to improve our understanding of how the public feels about sharing patient data alongside tissue that is donated for research, and their understanding and views on the different ways in which consent can be given.

48. We participated in six public dialogue workshops (the last of which took place in quarter one), held as a key part of the project. The workshops encouraged discussion with clinical researchers, industry representatives and regulators, and explored the perspectives of different stakeholder groups and the general public.

49. A joint report on the project is due to be published in quarter two.

Stakeholder and Fees Group

50. A Stakeholder and Fees Group meeting took place on 9 May. The group discussed:
   
a. Better Regulation initiatives
b. Coding and import Directives
c. The information contained in HTA inspection reports
d. Findings from the Codes and Standards post-implementation review
e. Findings from the stakeholder engagement survey circulated in quarter four
f. The Department for Health and Social Care’s consultation on an opt-out system of organ donation in England (which was presented by a member of the DHSC policy team)

51. The meeting was well attended and we will continue to look at ways to facilitate participation remotely to maintain engagement.
Delivery KPI narrative

Performance against 2018/19 KPIs

52. KPI 4 was green in April and red for May and June. In May, four out of 13 major and critical shortfalls were completed on time. CAPA evidence was due against a further nine major shortfalls, but was not received on time from the establishments. This was followed up appropriately. In June, eight out of nine major and critical shortfalls were completed on time. One was completed 12 days after the deadline as the establishment had seven shortfalls and submitted the evidence against each shortfall simultaneously. This meant the review of the information went beyond the deadline.

53. All other Delivery KPIs for quarter one 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>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 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>40</td>
<td>29</td>
<td>38</td>
<td>41</td>
<td>150</td>
<td>136</td>
<td>164</td>
</tr>
<tr>
<td>LAAV - new application</td>
<td>2</td>
<td>4</td>
<td>4</td>
<td>3</td>
<td>11</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>LAAV – variation</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Satellite site inspection</td>
<td>14</td>
<td>17</td>
<td>10</td>
<td>23</td>
<td>66</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td>CAPA follow up</td>
<td>1</td>
<td>0</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Non-routine inspection</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td><strong>Total sites visited</strong></td>
<td><strong>58</strong></td>
<td><strong>50</strong></td>
<td><strong>55</strong></td>
<td><strong>72</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

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

55. 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 an HTARI. Further detail on each case can be found in Annex B.

56. 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>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>2017/18 Total</th>
<th>2016/17 Total</th>
<th>2015/16 Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental damage to a body</td>
<td>12</td>
<td>16</td>
<td>15</td>
<td>7</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>1</td>
<td>0</td>
<td>0</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>4</td>
<td>0</td>
<td>0</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>1</td>
<td>1</td>
<td>2</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>1</td>
<td>2</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>1</td>
<td>1</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>6</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Major equipment failure</td>
<td>3</td>
<td>4</td>
<td>3</td>
<td>0</td>
<td>8</td>
<td>8</td>
<td>8</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>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>
Table Two B: Reported HTARIs in the post-mortem sector

57. This table shows all incidents reported to the HTA as HTARIs. This also includes any near misses and incidents that were, on investigation, found to be non-RIs.

Table Three: Closed SAEARs in the human application sector

58. 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.

59. 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.

60. 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 Three B: Reported SAEARs in the human application sector

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

<table>
<thead>
<tr>
<th>Type of Event or Reaction</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 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>0</td>
<td>0</td>
<td>0</td>
<td>1</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>1</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>7</td>
<td>7</td>
<td>3</td>
<td>3</td>
<td>21</td>
<td>13</td>
<td>5</td>
</tr>
<tr>
<td>Event linked to Procurement</td>
<td>14</td>
<td>4</td>
<td>7</td>
<td>5</td>
<td>18</td>
<td>11</td>
<td>18</td>
</tr>
<tr>
<td>Event linked to Storage</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>10</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>Event linked to Testing</td>
<td>5</td>
<td>0</td>
<td>2</td>
<td>2</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>1</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Event linked to Other process</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>4</td>
<td>8</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total – Events</strong></td>
<td>30</td>
<td>13</td>
<td>17</td>
<td>22</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>1</td>
<td>2</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>7</td>
<td>10</td>
<td>8</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total – Reactions</strong></td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>8</td>
<td>12</td>
<td>8</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total – Events and Reactions</strong></td>
<td>32</td>
<td>14</td>
<td>17</td>
<td>30</td>
<td>79</td>
<td>60</td>
<td>58</td>
</tr>
</tbody>
</table>
Table Four: Closed SAEARs in the Organ Donation and Transplantation sector

62. 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).

63. 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.

64. 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>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 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>2</td>
<td>7</td>
<td>5</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>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Reaction in Recipient</td>
<td>5</td>
<td>5</td>
<td>6</td>
<td>4</td>
<td>17</td>
<td>18</td>
<td>11</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7</strong></td>
<td><strong>12</strong></td>
<td><strong>12</strong></td>
<td><strong>11</strong></td>
<td><strong>47</strong></td>
<td><strong>46</strong></td>
<td><strong>42</strong></td>
</tr>
</tbody>
</table>

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

65. 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>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 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>6</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>22</td>
<td>38</td>
<td>22</td>
</tr>
<tr>
<td>Number of reported ODT SARs</td>
<td>9</td>
<td>3</td>
<td>8</td>
<td>3</td>
<td>15</td>
<td>26</td>
<td>14</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>15</strong></td>
<td><strong>6</strong></td>
<td><strong>11</strong></td>
<td><strong>8</strong></td>
<td><strong>37</strong></td>
<td><strong>64</strong></td>
<td><strong>36</strong></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 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>13</td>
<td>14</td>
<td>14</td>
<td>17</td>
<td>59</td>
<td>69</td>
<td>55</td>
</tr>
</tbody>
</table>
Table Six: Living organ donation cases

<table>
<thead>
<tr>
<th></th>
<th>Type of case</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Number of cases considered</th>
<th>Approvals by the Living Donation Assessment Team</th>
<th>Approvals by Authority panels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Directed kidney</td>
<td>Directed altruistic kidney</td>
<td>Non-directed altruistic kidney</td>
<td>Paired or pooled kidney</td>
<td>Directed liver lobe</td>
<td>Non-directed altruistic liver lobe</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LDAT Panel LDAT Panel</td>
<td>Panel</td>
<td>Panel</td>
<td>Panel</td>
<td>Panel</td>
<td>Panel</td>
<td>Panel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q1 18/19</td>
<td>211 1 5 1 20 61 4 0 1</td>
<td>304</td>
<td>220</td>
<td>84</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q4 17/18</td>
<td>208 1 2 3 15 45 8 0 0</td>
<td>282</td>
<td>218</td>
<td>64</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q3 17/18</td>
<td>208 0 1 1 25 62 12 0 1</td>
<td>310</td>
<td>221</td>
<td>89</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Q2 17/18</td>
<td>210 0 2 1 33 43 6 0 8</td>
<td>303</td>
<td>218</td>
<td>85</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17/18 Total Year</td>
<td>855 1 6 5 98 201 36 0 12</td>
<td>1214</td>
<td>897</td>
<td>317</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16/17 Total Year</td>
<td>874 21 10 3 91 113 46 0 5</td>
<td>1163</td>
<td>930</td>
<td>233</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15/16 Total Year</td>
<td>886 0 7 1 88 146 42 0 2</td>
<td>1172</td>
<td>935</td>
<td>237</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Communications

Social media

66. In quarter one, the HTA’s Twitter account had 1959 followers, up from 1896 in the previous quarter. Our engagement rate decreased to 1% from 1.3% during quarter 1, with a peak rate of 5%.

67. On average, HTA tweets were seen by 814 people per day, decreased slightly from 823 in quarter four.

Table Seven:

<table>
<thead>
<tr>
<th>Month</th>
<th>Impressions</th>
<th>Profile Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>April</td>
<td>20K</td>
<td>1,267</td>
</tr>
<tr>
<td>May</td>
<td>24.7K</td>
<td>1,434</td>
</tr>
<tr>
<td>June</td>
<td>29.5K</td>
<td>1,188</td>
</tr>
</tbody>
</table>

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

   a. Corporate
      The public Authority meeting
   b. Corporate
      70th anniversary of the NHS
   c. Post mortem
      Dying Matters Awareness Week
   d. Organ donation
      Encouraging people to talking about their organ donation decision
   e. Corporate
      Invitation to join the public panel
   f. Corporate
      Information about the establishment button
   g. Corporate
      Recruitment for the Board Secretary role

69. There are 805 Facebook ‘likes’ on the HTA page, up from 775 in last quarter. The HTA also had 563 followers for its LinkedIn company page, up from 541 last quarter.

Digital communications and publications
Table Nine: Website users

<table>
<thead>
<tr>
<th></th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>2017/18 Total Year</th>
<th>2016/17 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Users</td>
<td>69,168</td>
<td>69,818</td>
<td>55,723</td>
<td>49,725</td>
<td>237,457</td>
<td>199,226</td>
</tr>
<tr>
<td>Page views</td>
<td>263,278</td>
<td>300,228</td>
<td>243,507</td>
<td>214,622</td>
<td>949,008</td>
<td>781,047</td>
</tr>
<tr>
<td>Pages viewed per session</td>
<td>2.25</td>
<td>2.51</td>
<td>2.69</td>
<td>2.95</td>
<td>2.79</td>
<td>3.13</td>
</tr>
<tr>
<td>Average session duration</td>
<td>00:01:46</td>
<td>00:02:12</td>
<td>00:02:27</td>
<td>00:02:33</td>
<td>00:02:29</td>
<td>00:02:50</td>
</tr>
<tr>
<td>Online enquiries</td>
<td>284</td>
<td>355</td>
<td>289</td>
<td>268</td>
<td>1,146</td>
<td>1,396</td>
</tr>
<tr>
<td>eNewsletter signups</td>
<td>431</td>
<td>432</td>
<td>396</td>
<td>381</td>
<td>1,552</td>
<td>1,515</td>
</tr>
</tbody>
</table>

70. The highest viewed pages are:

Table Ten: Page views

<table>
<thead>
<tr>
<th>Highest viewed pages</th>
<th>Q1 2018/19</th>
<th>Q4 2017/18</th>
<th>Q3 2017/18</th>
<th>Q2 2017/18</th>
<th>2016/17 Total Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body donation FAQs</td>
<td>6,415</td>
<td>10,281</td>
<td>8,478</td>
<td>7,518</td>
<td>59,753</td>
</tr>
<tr>
<td>Medical school search</td>
<td>13,523</td>
<td>17,089</td>
<td>12,772</td>
<td>13,493</td>
<td>57,040</td>
</tr>
<tr>
<td>Donating your body info</td>
<td>27,737</td>
<td>22,866</td>
<td>17,042</td>
<td>17,241</td>
<td>40,819</td>
</tr>
<tr>
<td>Guidance for professionals</td>
<td>4,694</td>
<td>5,746</td>
<td>5,664</td>
<td>5,368</td>
<td>22,847</td>
</tr>
</tbody>
</table>

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

   a. Guidance for professionals – 13% of clicks on the homepage
   b. Codes of Practice and Standards – 12%; and
   c. How to donate your body – 8%.

72. We are continuing to see an increase in activity on our licensed establishment pages, which can be attributed to the increased use of our establishment button.

Newsletters

73. The HTA sent out a professional newsletter in May and a Living Donation News bulletin in May. The HTA public newsletter was sent out in June.

---

2 Data first collected in 2016/17
74. The government average is for 24% of subscribers to open newsletters.

Table 11: Professional newsletter UPDATE

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2018</td>
<td>4327</td>
<td>34%</td>
</tr>
<tr>
<td>March 2018</td>
<td>4318</td>
<td>31%</td>
</tr>
<tr>
<td>January 2018</td>
<td>4181</td>
<td>34%</td>
</tr>
<tr>
<td>November 2017</td>
<td>4176</td>
<td>32%</td>
</tr>
<tr>
<td>September 2017</td>
<td>3133</td>
<td>30%</td>
</tr>
<tr>
<td>July 2017</td>
<td>3076</td>
<td>28%</td>
</tr>
</tbody>
</table>

Table 12: Living Donation News bulletin UPDATE

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2018</td>
<td>266</td>
<td>35.8%</td>
</tr>
<tr>
<td>January 2018</td>
<td>268</td>
<td>44%</td>
</tr>
<tr>
<td>November 2017</td>
<td>272</td>
<td>35%</td>
</tr>
<tr>
<td>July 2017</td>
<td>272</td>
<td>25.7%</td>
</tr>
<tr>
<td>May 2017</td>
<td>273</td>
<td>31.5%</td>
</tr>
<tr>
<td>January 2017</td>
<td>261</td>
<td>48%</td>
</tr>
</tbody>
</table>

Table 13: Public newsletter UPDATE

<table>
<thead>
<tr>
<th>Month</th>
<th>Recipients</th>
<th>Open rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2018</td>
<td>1371</td>
<td>49%</td>
</tr>
<tr>
<td>February 2018</td>
<td>1249</td>
<td>39.8%</td>
</tr>
<tr>
<td>December 2017</td>
<td>1163</td>
<td>38%</td>
</tr>
<tr>
<td>October 2017</td>
<td>1086</td>
<td>29%</td>
</tr>
<tr>
<td>July 2017</td>
<td>997</td>
<td>42%</td>
</tr>
<tr>
<td>April 2017</td>
<td>903</td>
<td>49%</td>
</tr>
</tbody>
</table>

Media coverage

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

a. HTA statement for The Sunday Times: Pharmacells Ltd and Precious Cells International Ltd (PCI) entering administration

Following concerns raised about the services provided by Pharmacells Ltd and
Precious Cells International, the HTA were made aware that they would be ceasing their operations and both establishments would be entering administration (Pharmacells is owned by PCI).

- Probe launched over babies stem cell storage ‘failure’ (Sunday Times, 1 April 2018)
- Stem cells for babies ‘ruined by failed lab’ (The Times, 2 April 2018)

b. Coverage on the proposal for Britain’s first human taphonomy facility (commonly referred to as a ‘body farm’)

- Britain’s first ‘body farm’: Police will solve murders by leaving dead volunteers to decompose in a field (The Telegraph)
- Home Office considering plans to open body farms (Police Oracle)
- Missing: One Human Decomposition Facility (The Pathologist)

c. Coverage of cryopreservation

- This Is What You Need to Do to Get Cryogenically Frozen in the UK (Vice)

d. Coverage of cord blood banking

- Cord Blood Banking Services Market to be Driven by the Increasing Number of Applications Available for Cord Blood (Facts Week)
Annex B – Closed SAEARs, ODT SAEARs and 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-39288-W9M1</td>
<td>Processing</td>
<td>One of two reagents used in sterility testing appeared darker than normal and did not support growth of Clostridium sporogenes. Assessment of all tissues and cells already tested with this media undertaken and either re-tested, disposed, patient monitored or marked for concessionary release.</td>
</tr>
<tr>
<td>CAS-40411-Q3T7</td>
<td>Testing</td>
<td>A donor of cells for ATMP was not subjected to mandatory biological tests on the day of donation. This was due to incorrect procedures.</td>
</tr>
<tr>
<td>CAS-39053-K8R4</td>
<td>Procurement</td>
<td>Unlicensed procurement of cord blood undertaken by clinician due to complications during child birth. Unit successfully banked.</td>
</tr>
<tr>
<td>CAS-40253-P2B4</td>
<td>Procurement</td>
<td>Unlicensed procurement of cord blood by clinician because client did not give licensed phlebotomist sufficient warning that labour had progressed. Procurement of cord tissue undertaken by phlebotomist and both units successfully banked.</td>
</tr>
<tr>
<td>CAS-40557-C8T1</td>
<td>Storage</td>
<td>Cranial flap not sent for autoclaving as per SOP; remained in theatre refrigerator. SOPs reviewed and made available to all staff, daily refrigerator checks implemented.</td>
</tr>
<tr>
<td>CAS-41804-P1H4</td>
<td>Processing</td>
<td>Wrong volume of bag was written on the PBSC collection resulting in the incorrect addition of cryoprotectant and consequently low cell viability. Procedures have been amended to included weighing of all bags prior to cryopreservation.</td>
</tr>
<tr>
<td>CAS-41255-G8F5</td>
<td>Processing</td>
<td>One imported and infused cord blood unit was not correctly labelled and therefore was not the correct haplotype. This was a double cord transplant and the other cord engrafted successfully.</td>
</tr>
<tr>
<td>CAS-43106-J6B2</td>
<td>Testing</td>
<td>Positive bacteriology results for a red cell depleted BM were sent to the wrong address and therefore did not reach the processing facility until 7 days later than they should have. Stem cells currently stored as back-up, results to be discussed with clinician if requested for release. Addresses checked and confirmation of receipt of results added to process.</td>
</tr>
<tr>
<td>CAS-43649-P1B2</td>
<td>Procurement</td>
<td>Anticoagulant was not added during the harvesting process as the ACDA seal was not broken, resulting in coagulation of the product. Through the change control process, staff have been notified and trained around ensuring the seal is broken during the procedure and the relevant SOP updated.</td>
</tr>
<tr>
<td>CAS-41921-G8B9</td>
<td>Testing</td>
<td>Related to PBSC incomplete testing for HepB antigen intended for use as a starting material for ATMP product. Testing virology panels were updated to reflect HTA requirements and training provided to staff to include testing required and timelines.</td>
</tr>
<tr>
<td>CAS-43054-L8M9</td>
<td>Procurement</td>
<td>Bone marrow contamination with gram positive rods during harvest. Patient did not develop infection following receipt of product.</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-43943-Q0S0</td>
<td>Procurement</td>
<td>Procured cord blood was not secured or packaged correctly leading to leakage and loss of the unit</td>
</tr>
<tr>
<td>CAS-42663-N2G2</td>
<td>Transportation</td>
<td>Transplanted islet preparation was contaminated with Candida Albicans. The same organism was also detected in a sample of transport fluid in which the pancreas was shipped from the retrieval hospital.</td>
</tr>
<tr>
<td>CAS-42004-J4P2</td>
<td>Other (please specify)</td>
<td>Transplant centre reported positive sterility result for imported bone marrow. Collection centre samples were negative. Recipient was unaffected.</td>
</tr>
<tr>
<td>CAS-43729-K5M1</td>
<td>Processing</td>
<td>Contaminant detected in C grade clean room area and A grade cabinet. The laboratory have taken a number of steps to eliminate any potential sources. There has not been a reoccurrence for several weeks.</td>
</tr>
<tr>
<td>CAS-40161-N1X7</td>
<td>Other (please specify)</td>
<td>Bone Marrow allogeneic donation had gram positive cocci samples pre and post processing. Practices for procurement and processing reviewed and actions taken. This SAE has been linked to five other similar cases.</td>
</tr>
<tr>
<td>CAS-40456-B9G0</td>
<td>Processing</td>
<td>Contamination of PBSCs during processing. The product was concessionary released and the recipient has engrafted. This SAE has been linked to five other similar cases.</td>
</tr>
<tr>
<td>CAS-40895-H5F9</td>
<td>Processing</td>
<td>Post processing sample of PBSC contaminated however pre processing and post infusion samples clear. Poor engraftment probably due to underlying medical condition. This SAE has been linked to five other similar cases.</td>
</tr>
<tr>
<td>CAS-43645-K9D8</td>
<td>Procurement</td>
<td>Spillage of bone marrow product during harvest; released under concession due to low cell numbers. Staff to receive additional training.</td>
</tr>
<tr>
<td>CAS-43646-K4G2</td>
<td>Procurement</td>
<td>Bone marrow contamination during harvest originating from an overseas collection centre.</td>
</tr>
<tr>
<td>CAS-40408-L0N7</td>
<td>Procurement</td>
<td>Positive microbiology of PBSCs with gram positive cocci. PBSCs procured in an overseas collection centre. Transplant centre has been notified and the recipient has engrafted.</td>
</tr>
<tr>
<td>CAS-43035-L9K6</td>
<td>Procurement</td>
<td>Loss of BM product during RBC-depletion due to misalignment of kit on the apheresis machine. Second person check implemented to ensure correct kit placement for future processing.</td>
</tr>
<tr>
<td>CAS-43064-W9X7</td>
<td>Procurement</td>
<td>Loss of BM product during RBC-depletion due to misalignment of kit on the apheresis machine. Second person check implemented to ensure correct kit placement for future processing.</td>
</tr>
<tr>
<td>CAS-35831-V3Z1</td>
<td>Processing</td>
<td>Delayed reporting of positive bacteriology of BM product to overseas transplant centre. SOP amended to contact registries immediately in the event of a positive notification to suitable prophylaxis treatment. No follow up report as the QM was replaced.</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-43434-G4T1</td>
<td>Procurement</td>
<td>A potential mix-up of cord blood/tissue due to the tray holding the tissue not being labelled occurred. DNA testing offered to confirm the identity of the tissue but not taken up. Updated instruction sheets and risk assessments as well as re-training of all staff involved with this procedure.</td>
</tr>
<tr>
<td>CAS-43430-Q8P1</td>
<td>Testing</td>
<td>False positive nucleic acid test result (autologous donor) from testing lab.</td>
</tr>
<tr>
<td>CAS-42357-H2J7</td>
<td>Testing</td>
<td>False negative mandatory marker result.</td>
</tr>
<tr>
<td>CAS-43011-S1V3</td>
<td>Procurement</td>
<td>Allogeneic bone marrow harvest resulted in bacterial contamination which was identified by the transplant centre during pre and post processing. The patient was given antibiotics resulting in no adverse reactions.</td>
</tr>
<tr>
<td>CAS-43007-T7V4</td>
<td>Procurement</td>
<td>Allogeneic bone marrow harvest resulted in bacterial contamination which was identified by the transplant centre during pre and post processing. The patient was given antibiotics resulting in no adverse reactions.</td>
</tr>
<tr>
<td>CAS-43553-G0N5</td>
<td>Procurement</td>
<td>The collection centre for allogenic bone marrow harvest reported positive results for bacterial contamination. However, the transplant centre reported negative results and the patient received prophylactic antibiotics as a precaution.</td>
</tr>
</tbody>
</table>

**Human Application – Serious Adverse Reactions**

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Donor or Recipient</th>
<th>Description of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-39892-W6Z5</td>
<td>Recipient</td>
<td>Recipient reacted to infusion of fresh stem cells as the donation had high levels of anti-A and B titres due to donor-recipient minor ABO incompatibility. The side effects included rigors and elevated temperature and the recipient required oxygen.</td>
</tr>
<tr>
<td>CAS-39883-X5P9</td>
<td>Recipient</td>
<td>Recipient reacted to infusion of fresh stem cells as the donation had high levels of anti-A and B titres due to donor-recipient minor ABO incompatibility.</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-44425-X2W7</td>
<td>ODT SAE</td>
<td>Damage to organ - not transplanted</td>
</tr>
<tr>
<td>CAS-44586-K5J4</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-44464-S5Q3</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Damage to organ - recipient impacted</td>
</tr>
<tr>
<td>CAS-41707-K3Z2</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Possible donor infection transmission</td>
</tr>
<tr>
<td>CAS-41706-G7Q0</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Possible donor infection transmission</td>
</tr>
<tr>
<td>CAS-42127-D8P3</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Possible donor infection transmission</td>
</tr>
<tr>
<td>CAS-44122-N5G3</td>
<td>Recipient</td>
<td>ODT SAR</td>
<td>Complications experienced post-transplant - recipient impacted</td>
</tr>
</tbody>
</table>
**Post Mortem HTA Reportable Incidents**

<table>
<thead>
<tr>
<th>Case Number</th>
<th>Incident Classification</th>
<th>Brief summary of HTARI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS-42168-Q6B3</td>
<td>Accidental damage to a body</td>
<td>Accidental damage to body due to contact with the fridge racking.</td>
</tr>
<tr>
<td>CAS-42058-V2B2</td>
<td>Accidental damage to a body</td>
<td>Unusual body morphology lead to accidental damage to a body.</td>
</tr>
<tr>
<td>CAS-42123-D3W7</td>
<td>Any incident not listed here that could result in adverse</td>
<td>Administrative error led to a missed opportunity for parents to attend a funeral</td>
</tr>
<tr>
<td></td>
<td>publicity that may lead to damage in public confidence</td>
<td>service</td>
</tr>
<tr>
<td>CAS-42167-H0P9</td>
<td>Accidental damage to a body</td>
<td>Accidental damage to a body due to a tray above falling.</td>
</tr>
<tr>
<td>CAS-37419-M0M9</td>
<td>Any incident not listed here that could result in adverse</td>
<td>Procedural error led to misfiling and loss of archived PM blocks and slides.</td>
</tr>
<tr>
<td></td>
<td>publicity that may lead to damage in public confidence</td>
<td></td>
</tr>
<tr>
<td>CAS-40649-X5S2</td>
<td>Any incident not listed here that could result in adverse</td>
<td>Human error led to the documented procedure for viewings not being followed.</td>
</tr>
<tr>
<td></td>
<td>publicity that may lead to damage in public confidence</td>
<td></td>
</tr>
<tr>
<td>CAS-42435-S8Y8</td>
<td>Accidental damage to a body</td>
<td>Difficulty placing a patient into the fridge lead to the body slipping off the tray and onto the floor causing damage.</td>
</tr>
<tr>
<td>CAS-42927-H7Z0</td>
<td>Any incident not listed here that could result in adverse</td>
<td>Family complained about the condition of deceased and there was some media coverage.</td>
</tr>
<tr>
<td></td>
<td>publicity that may lead to damage in public confidence</td>
<td></td>
</tr>
<tr>
<td>CAS-43569-Y2C6</td>
<td>Serious security breach</td>
<td>An individual gained access to the mortuary by following a funeral director into the building. They were removed from the building immediately.</td>
</tr>
<tr>
<td>CAS-41972-W0T3</td>
<td>Viewing of the wrong body</td>
<td>Failure in procedures led to viewing of the wrong body</td>
</tr>
<tr>
<td>CAS-40247-C2R2</td>
<td>Any incident not listed here that could result in adverse</td>
<td>Human error led to a body being left in the viewing room for longer than required.</td>
</tr>
<tr>
<td></td>
<td>publicity that may lead to damage in public confidence</td>
<td></td>
</tr>
<tr>
<td>CAS-42439-F7R5</td>
<td>Major equipment failure</td>
<td>Freezer failure in the mortuary. There was no significant damage to bodies.</td>
</tr>
<tr>
<td>CAS-42442-W4M5</td>
<td>Major equipment failure</td>
<td>Due to a power outage, the extractor fan in the PM stopped working. PM examinations were delayed.</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-42675-Z0D5</td>
<td>Release of the wrong body</td>
<td>Due to human error the wrong body was released. The body was returned to the mortuary as soon as the incident was discovered.</td>
</tr>
<tr>
<td>CAS-43737-D9C6</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Unauthorised pictures were taken of a deceased at a viewing.</td>
</tr>
<tr>
<td>CAS-43983-J1M1</td>
<td>Accidental damage to a body</td>
<td>Human error led to accidental damage to a deceased person.</td>
</tr>
<tr>
<td>CAS-42996-L7D4</td>
<td>Accidental damage to a body</td>
<td>Procedural error led to minor damage to a deceased person whilst being transferred into the mortuary.</td>
</tr>
<tr>
<td>CAS-44345-H5P0</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Complaint received about use of social media.</td>
</tr>
<tr>
<td>CAS-42376-G5J3</td>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>Due to human error an organ was not returned to the body before disposal.</td>
</tr>
<tr>
<td>CAS-43902-F5P7</td>
<td>Serious security breach</td>
<td>Access to the mortuary inappropriately authorised</td>
</tr>
<tr>
<td>CAS-43716-V6J9</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-41290-B8M8</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 SOP not being followed for a release of the deceased</td>
</tr>
<tr>
<td>CAS-43393-F6T0</td>
<td>Major equipment failure</td>
<td>Fridge failure resulted in transfer of bodies to another HTA licensed establishment.</td>
</tr>
<tr>
<td>CAS-43249-J0L1</td>
<td>Accidental damage to a body</td>
<td>Human error led to damage to a deceased person during a post-mortem examination.</td>
</tr>
<tr>
<td>CAS-39940-F0V2</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Human error lead to loss of patient property</td>
</tr>
<tr>
<td>CAS-40426-C5J5</td>
<td>Accidental damage to a body</td>
<td>Human error led to minor damage to a deceased person whilst being transferred into the mortuary.</td>
</tr>
<tr>
<td>CAS-41030-Z7K0</td>
<td>Loss of an organ</td>
<td>Human error lead to loss of part of an organ</td>
</tr>
<tr>
<td>CAS-41457-K0W1</td>
<td>Accidental damage to a body</td>
<td>Human error led to minor damage to a deceased person whilst being transferred into the mortuary.</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-42210-K7G7</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 lead to the retention of tissue following the return of all other tissues to the family.</td>
</tr>
<tr>
<td>CAS-42977-J8T8</td>
<td>Release of the wrong body</td>
<td>Human error lead to the short term release of a wrong body.</td>
</tr>
<tr>
<td>CAS-42523-W9T4</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-42026-Y1J9</td>
<td>Post-mortem examination conducted was not in line with the consent given or the post-mortem examination proceeded with inadequate consent</td>
<td>Failures in communication procedures led to a PM examination being commenced without authority.</td>
</tr>
<tr>
<td>CAS-44485-L8B7</td>
<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>Human error lead to the retention of a whole fetus (less than 24 weeks) against the express wishes of the family</td>
</tr>
<tr>
<td>CAS-42770-F4S1</td>
<td>Accidental damage to a body</td>
<td>Accidental damage to hand caused by porter</td>
</tr>
<tr>
<td>CAS-41905-L0F0</td>
<td>Viewing of the wrong body</td>
<td>Viewing of the wrong body with same/similar name</td>
</tr>
<tr>
<td>CAS-41882-V9V1</td>
<td>Accidental damage to a body</td>
<td>Paediatric body received a post mortem skull fracture.</td>
</tr>
<tr>
<td>CAS-44692-W6R3</td>
<td>Accidental damage to a body</td>
<td>Due to staff not following procedures, the arm of the deceased may have been damaged when placing the body into the fridge.</td>
</tr>
<tr>
<td>CAS-43278-W4V6</td>
<td>Any incident not listed here that could result in adverse publicity that may lead to damage in public confidence</td>
<td>Lack of procedure resulted in confusion over tissue repatriated to the UK.</td>
</tr>
</tbody>
</table>
### Authority Report

**Development – Quarter One 2018/19**

<table>
<thead>
<tr>
<th>Date</th>
<th>19 July 2018</th>
<th>Paper Reference</th>
<th>HTA (22/18)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agenda Item</td>
<td>8</td>
<td>Author</td>
<td>Hazel Lofty</td>
</tr>
<tr>
<td>Protective Marking</td>
<td>OFFICIAL</td>
<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)

- **a)** Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
- **b)** Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;
- **c)** Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements;
- **d)** 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

#### 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 20a/18 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was approved by the CEO on 12 July 2018 for submission to the Authority.

Action required

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

Director’s summary

5. Good progress has been made in development projects in quarter 1, including planning for future quarters.

6. Speed of progress in our regulatory development activity has been hampered by loss of staff in some key posts. Now that new permanent Directors have taken up their posts and the new organisational structure has come into effect, we would anticipate being better placed to more flexibly deploy people to organisational priorities over the coming six months.

Core 2018/19 projects

7. The three projects below are considered core during 2018/19.

EU Coding and Import Directives implementation

8. In quarter one, progress has been made on completing the outstanding development work from the implementation of the European Union Coding and Import Directives. This has included modifying the licence application and variation process for import establishments and developing associated guidance and governance documents.

9. It is anticipated that further training of Regulation Mangers will be undertaken in quarter two. This will be aimed at further embedding the changes, but will also ensure that new staff are aware of the requirements.

10. There are some residual systems changes to be made to CRM in order to be able to distinguish between the different types of import activity that establishments are
licensed to carry out. It is anticipated that these changes will be put in place following completion of the CRM upgrade.

11. During implementation, a risk-based approach was adopted whereby the majority of importing establishments received an updated import licence with a Corrective and Preventative Action (CAPA) Plan. Where this was the case, we issued a fixed term Import Tissue Establishment Certificate (ITELC) pending completion of the CAPA. Management of these CAPA plans has been ongoing throughout quarter one and we anticipate that all importing establishments will have been issued with a continuous ITELC by the 1 August 2018.

12. A total of 17 establishments in the Human Application sector were inspected in quarter one, including six import establishments. We will review inspection outcomes of these establishments to consider any impact of implementation, in particular with respect to post-inspection workload. This information will also be used to inform future resource planning.

Licensed establishment relationship programme

13. Work continues on the development of online tests on the three main pieces of HTA legislation (HT Act, Q&S Regulations and ODT Regulations) to supplement the information for Designated Individuals and licence contacts on the HTA website.

14. During Q1, the ODT Regulations test underwent testing and review internally by the Regulation Team and is now ready to publish and promote through our online channels. The Q&S Regulations test is still undergoing internal review by Heads and staff and we intend to make the test available publicly before the end of Q2.

15. The programme continues to oversee the development of an online forum for professionals. As part of the alpha testing stage, two prototypes of the forum have been tested so far with volunteer licence contacts in the Post Mortem and Research sectors. The first was based on a collaboration tool called ‘Slack’. The second model was created on our website to ensure accessibility to all.

16. We have had more positive feedback on the latter model from users, with the majority of those testing saying that they would use the service, and that the forum was easy and intuitive to navigate. However, we received additional feedback showing ways we can adapt this web-based forum to deliver desirable features including:

   a. an assurance mechanism for the reliability of the information posted on the forum; and
   b. a way to ensure that the forum stays active.
17. During Q2 and based on the feedback we have received, we will create a third model featuring the HTA acting as more of a forum participant, rather than a moderator. This should help to ensure that the forum stays more active and that the information posted is of high quality. We anticipate that this model will be the final one that we test as part of the alpha-stage.

18. During Q1, the programme began to scope the extent and nature of issues around establishments’ understanding of HTA licensing requirements. The main areas of concern that have been determined are:

   a. Establishments undertaking licensable activities and not having a licence.
   b. Establishments having an HTA licence, but not being licensed for the correct activities.

19. The project team has also mapped out broad areas on which to build a targeted communications strategy. We will look at the extent to which:

   a. Establishments are not aware of the HTA’s licensing requirements at all
   b. Establishments are aware of the HTA’s licensing requirements, but they don’t understand them – or they are not clear; or if
   c. Establishments are aware of the HTA’s licensing requirements, but choose not to undertake the licensing – i.e., ignore the requirements or seek to circumvent them.

20. We have sought input from Regulation Managers regarding establishment case studies and assessing which sectors predominantly experience these issues in order to map out where the problems inherently lie. As part of this work, we will also assess the data we have from past police referral cases.

21. We will also seek feedback on from licensed establishments themselves via an online survey and we will consult the licensed establishment engagement panel at the next external meeting during Q2.

Assessment of risk in the human application sector

22. As previously set out, we anticipate that implementation of the recommendations arising from the HA risk project will begin in quarter three.

23. A preliminary mapping exercise of the HA sector is ongoing and will be concluded in quarter two. This is to compare the breadth and types of licensable activities being undertaken at satellite licences and by third parties.
24. An update on the oversight strategy for licensable activities carried out by third parties was presented to the Audit Risk and Assurance Committee in June 2018.

Organisational Transformation Programme

25. Planning work has begun for the Transformation Programme to 2021. An update will be provided at item 13 of the July Authority meeting *Route Map to 2021*.

Additional 2018/19 projects

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

Horizon scanning

27. In Q1 work on horizon scanning has focused on updating our map of information sources and outputs, and meeting with Heads of Regulation to check for any gaps and sense check this piece of work. The next and most significant step in this programme of work is to move horizon scanning to a “business as usual” process for the organisation.

28. In Q1 it was determined that the horizon map focusses solely on sector specific information sources and potential risks. It has been reviewed and amended to incorporate wider corporate sources, such as those relating to data protection and cyber security.

29. It has been agreed that the map will be a living document that will be reviewed regularly by the project lead and the Head responsible for each area.

30. The success measure for the outcomes of this project will be twofold:

   a. that new staff coming into the organisation can pick up the work of their predecessor with minimal burden, and
   b. we can chart and measure which outputs were a result of which horizon scanning activity. We expect to be in this position by the end of Q3 this year, a timescale that allows for the bedding in of the process, as well as accounting for staff changes.

Development of a safety KPI

31. A report is to be provided to the Authority on an annual basis describing each of the assurance measures that the HTA uses to assure that human tissue and organs are used safely, ethically and with proper consent.
32. This report will be presented for the first time for the 2017/18 business year. An overview of this is provided in HTA (27-18).

33. A full copy of the report will be provided in advance of the Authority’s annual Strategic Planning Away Day in September 2018.

34. The analysis of data for the 2017/18 report identified some limitations with the data recorded in CRM. This necessitated manual data extraction and collation for the majority of information within the report. These limitations link to a number of other business areas, for example reporting inspection outcomes as well as HTARI and SAEARs reporting. A workshop was held with Regulation Managers and the licensing team in quarter one to review CAPA management and identify any potential process changes. This work will be taken forward into quarter two in order to resolve the issues highlighted.

Sustainability of the Independent Assessors (IAs) framework

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

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

37. Analysis of this data demonstrated that there is some considerable variability in practice and arrangements across the country, particularly in terms of reimbursement of expenses. This analysis has informed options for consideration which were discussed in detail at the Transplantation Advisory Group meeting on 23 May 2018.

38. Full scoping of the project will take place in July and implementation of any subsequent changes will take place during the rest of the 2018/19 business year.

Post Mortem (PM) Sector development work

39. A series of recommendations for the ongoing regulation of the PM sector were approved by SMT in quarter one.

40. Work is ongoing to prioritise these recommendations into a work plan. This will be taken forward in quarter two once the Head of Regulation for the PM sector is in post.

Development KPI narrative
Performance against 2018/19 KPIs

41. KPI 8 Deliver a project to implement EU Directives on Coding and Import (Embedding of requirements (Q1 onwards) marked as amber as we are now post deadline, and the further work to embed the regulations is contingent on available staff resources and CRM upgrade.

42. All other Delivery KPIs for quarter one are within target or tolerance and/or marked as green.

Projects scheduled to start in the next six months

<table>
<thead>
<tr>
<th>Project</th>
<th>Brief description</th>
<th>Start date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory oversight of organ perfusion</td>
<td>Review of the current regulatory framework for the oversight of organ perfusion in the Organ Donation and Transplantation (ODT) sector</td>
<td>Q2 2018</td>
</tr>
</tbody>
</table>
## Strategic objectives (Deployment)

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>a)</td>
<td>Manage and develop our people in line with the HTA’s People Strategy;</td>
<td>Attraction rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly)</td>
</tr>
<tr>
<td>b)</td>
<td>Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money;</td>
<td>Percentage of Regulation Managers with more than one year of service (high risk if less than 80%) (reported quarterly)</td>
</tr>
<tr>
<td>c)</td>
<td>Provide a suitable working environment and effective business technology, with due regard for data protection and information security;</td>
<td>Plan for remodelling of RM induction and training programme (Q1) Roll out of new programme (Q4)</td>
</tr>
<tr>
<td>d)</td>
<td>Plan and prioritise our resources to carefully balance activity across the organisation.</td>
<td></td>
</tr>
</tbody>
</table>

## Relevant KPIs (marked as red, amber, green, black or blue)

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
<th>Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Reduce attrition rates through improved selection and targeted retention measures to retain staff</td>
<td></td>
</tr>
<tr>
<td>2.</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></td>
</tr>
<tr>
<td>3.</td>
<td>Lead and advise on best recruitment procedures to maintain organisational capacity and capability</td>
<td></td>
</tr>
<tr>
<td>4.</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></td>
</tr>
</tbody>
</table>

- 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)
5. 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).

<table>
<thead>
<tr>
<th>Related Strategic Risks (marked as red, amber or green)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 - Failure to manage an incident (all objectives)</td>
</tr>
<tr>
<td>4 - Failure to utilise our capabilities effectively (objectives a, c and d)</td>
</tr>
<tr>
<td>5 - Insufficient, or ineffective management of, financial resources (objective b)</td>
</tr>
</tbody>
</table>

(See paper 23a/18 for detailed information)
Purpose of paper

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

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

Decision-making to date

3. This report was approved by the CEO on 12 July 2018 for submission to the Authority.

Action required

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

Director’s summary

5. During quarter one, the final decision on the organisational structure was taken and shared with all staff on 18 June at a staff meeting and subsequently in the weekly newsletter. The most significant changes to result from the all staff one-to-ones were: the Head of Business Technology will report to the Director of Regulatory Development; we will retain separate Heads of function covering the HTAct sectors; and we will initially appoint to three Senior Regulation Manager posts in early autumn.

6. Nicky Harrison took up her role as Director of Regulatory Delivery on 4 June, and the creation of the single Regulation Directorate took effect from 2 July. Dr Amy Thomas was appointed permanently to the new Head of Development role and formally took up post on the same date.

7. Work is now in progress to embed the new organisational structure. This includes new arrangements for team meetings and a review of the collective role of the Senior Management Team and the HTA Management Group.

8. A number of interim appointments also ended on this date. Chris Birkett returned to his role as Head of Regulation (Research and Anatomy Sectors) and Dr Chitvan Amin returned to her role as Transplant Manager. Adam Whittaker will stay on in the role of Head of Regulation (Post Mortem and Public Display) until the end of July when we expect to have made the permanent appointment to this role.

9. There are continuing indications of difficulty in recruiting staff from outside the HTA to vacant posts. We are in the process of recruiting for the new Head of Operations post, the Head of Regulation (Post Mortem and Public Display) role, the new Board Secretary post and a number of RM vacancies.
10. Year to date expenditure is c£100k below the figure budgeted, this is primarily a result of staff vacancies and expenditure for inspection travel and annual conference which will now take place later in the year.

11. Following a review of quarter 1 expenditure and future plans we have undertaken our first forecast of our year end position, this initial position is that we will deliver a small surplus of £14k. We have identified some activities where we could utilise our emerging underspend and we will look take decisions in early September on the priority areas for additional funding.

People

People Strategy

12. The 2018-21 People Strategy is expected to be completed in the autumn following the Authority’s annual strategy away day. Until then the 2017-18 People Strategy remains an entirely relevant guide to our approach and we are continuing to work on a range of initiatives, some of which are outlined below.

Learning and Development

13. Following attendance on training courses, we ask staff to provide feedback via an online evaluation form, which allows us to monitor our performance against KPI 4 of our business plan, which requires 80% of staff to agree that the skills and knowledge gained will be useful for knowledge, performance, career development or general wellbeing. In 2017-18, 95% of staff who completed evaluation forms agreed that the skills and knowledge they gained would be useful to them.

14. Two issues associated with training during 2017-18. The first was that we saw an increasing trend towards late drop outs form group training courses. The second was the reducing proportion of staff completing evaluation forms. These issues present problems in achieving and assessing value for money (training spend was £24,000 last year) respectively. The management team intend to monitor these much more closely in 2018-19.

15. The 2018-19 training plan is currently being developed based on the HTA’s business plan and the training and development needs identified by line managers and staff during the annual Performance Development Plan (PDP) review process.

16. In addition to the overall staff training plan, we have committed to developing our line managers knowledge of HTA policies and management practices to ensure our staff are being treated in a consistent manner across the organisation. Delivery will be via our monthly HTAMG meetings with the first session having taken place in June. The
session focussed on the HTA’s leave policies including legal requirements, what the HTA offer and how the policies should be applied.

Equal opportunities report

17. The HTA produce an Equal Opportunities Report on an annual basis. The report analyses monitoring information that staff provide upon commencing employment with the HTA as well as monitoring information submitted by applicants as part of the recruitment process.

18. The purpose of the report is to identify any adverse detriment on any particular group of individuals, either during their employment or the recruitment process, and take action accordingly. The Civil Service is used as a comparator.

19. Analysis of data from the period April 2017 – March 2018 does not highlight any concerning trends that would indicate discrimination or bias. It is however important that the HTA continue to collect and monitor this data so that any concerning trends can be identified and addressed should they arise.

20. In 2018-19 the HTA will be delivering training on equality and diversity as part of its training programme for staff. This will be in addition to staff completing the online ‘Equality and Diversity Essentials’ learning module delivered via Civil Service Learning.

Pay Guidance 2018 to 2019

21. On 25 June, the Government published its pay guidance for 2018 to 2019. This year, government departments will be able to make average pay awards within the new range of 1 to 1.5 per cent.

22. The Remuneration Committee will be considering the Executive’s recommendations for the allocation of this award at its meeting on 23 July 2018. Further work will also now be required on the future shape of the HTA’s pay framework which is aligned with the Agenda for Change pay framework.

23. The pay guidance for Executive and Senior Managers (ESM) had not been published at the time this paper was produced.

Procurement of new HR system

24. At present, the HTA use a database called Simply Personnel to hold essential employee data and to manage and monitor annual leave and absences.
25. Simply Personnel has limited functionality, and this has meant that we are not always able to hold, manage and analyse employee data in the way we would like. In addition, due to the limited functionality, we are unable to reliably meet our obligations under GDPR in terms of data retention.

26. For these reasons, we will be replacing Simply Personnel with People HR. People HR will provide the HTA with a cost effective system that will enable us to meet our GDPR obligations as well as provide much greater functionality for HR, line managers and staff including all personnel information able to be held in one system, dashboards that will allow line managers to better monitor leave and absences and staff being given the option of a desktop site as well as a mobile app to manage their leave, review training records and to update their details. The system also offers functionality for claiming expenses while out on inspection, and this will be further investigated as part of the migration process.

27. We anticipate migrating to HR People by the end of quarter three, including training for managers and staff on how to use the system. HFEA are in the process of migrating to People HR at present and we will be in discussion with them to understand what went well and any lessons learnt.

Finance

Financial position for Q1 2018/19

28. For the first three months of the 2018/19 financial year we are showing a surplus against budget of £99k.

29. The table below show the summarised financial position as at 30 June 2018 which is made up of a small under recovery in our income of £5k and a significant underspend in revenue expenditure of £104k.
Summary - Income & Expenditure

For the Three Months Ending 30 June 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>(1,814,348)</td>
<td>(1,819,356)</td>
<td>5,008</td>
<td>-0.28%</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditure</td>
<td>1,110,618</td>
<td>1,215,190</td>
<td>(104,572)</td>
<td>-8.61%</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(703,730)</td>
<td>(604,166)</td>
<td>(99,564)</td>
<td>16.48%</td>
</tr>
</tbody>
</table>

Income

30. Income for the three months ended June is under budget by £5k. Our Grant in aid for the quarter has been drawn down and we have billed the first of the six sectors (Human Application). The deficit against budget of £23k within Human Application is largely due to a provision relating to three establishments who are either revoking licences or are in financial difficulty and the income is not expected to be received.

31. Against the shortfall in licence fee income we have a surplus within Other Income. This surplus is helped by an increase in our income from Devolved Governments where an uplift for inflation, which has been billed, was not budgeted for.

32. The income from rent and secondments are slightly skewed as the budget profile needs to be re-worked, this will be concluded for Q2.

33. Table two below shows the breakdown of income streams and their respective variances to budget.
Table Two: Income Summary

Member Income Summary

For the Three Months Ending 30 June 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>Grant In Aid</td>
<td>GIA</td>
<td>£176,000</td>
<td>£175,750</td>
<td>£250</td>
</tr>
<tr>
<td>Sub-Total</td>
<td></td>
<td>£176,000</td>
<td>£175,750</td>
<td>£250</td>
</tr>
<tr>
<td>Licence Fees</td>
<td>Application Fees</td>
<td>£11,390</td>
<td>£12,500</td>
<td>(£1,110)</td>
</tr>
<tr>
<td></td>
<td>Human application</td>
<td>£1,394,813</td>
<td>£1,417,870</td>
<td>(£23,057)</td>
</tr>
<tr>
<td>Sub-Total</td>
<td></td>
<td>£1,406,203</td>
<td>£1,430,370</td>
<td>(£24,167)</td>
</tr>
<tr>
<td>Other</td>
<td>Other income (Rent)</td>
<td>£75,793</td>
<td>£85,134</td>
<td>(£9,341)</td>
</tr>
<tr>
<td></td>
<td>Other income (Secondee)</td>
<td>£23,529</td>
<td>£9,431</td>
<td>£14,098</td>
</tr>
<tr>
<td></td>
<td>Devolved Assemblies</td>
<td>£132,823</td>
<td>£118,671</td>
<td>£14,152</td>
</tr>
<tr>
<td>Sub-Total</td>
<td></td>
<td>£232,145</td>
<td>£213,236</td>
<td>£18,909</td>
</tr>
<tr>
<td>Total Income</td>
<td></td>
<td>£1,814,348</td>
<td>£1,819,356</td>
<td>(£5,008)</td>
</tr>
</tbody>
</table>

34. The variance in application fees is minor; it has historically been difficult to predict accurately how many applications we are likely to receive.

Expenditure

35. Our total revenue expenditure is under budget by £104k with £49k relating to staff salaries and wages and the balance of £55k to Non-staff costs. Activity levels have been relatively stable in the first quarter. Table three below is a summary of expenditure.

36. Salaries and wage costs (£49k) where a majority of the underspend is within the Regulatory Delivery and Development directorates. In each the budget reflects posts at Manager and Head level that are currently vacant. In addition to carrying vacancies, the budget assumed full “on-costs” for all staff i.e. pension costs, however not all staff are in the pension scheme.
Table Three: Summary Expenditure

Summary - Expenditure

For the Three Months Ending 30 June 2018

<table>
<thead>
<tr>
<th>EXPENDITURE SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Costs</td>
</tr>
<tr>
<td>Non Staff Costs</td>
</tr>
<tr>
<td>Gross Costs before Exceptional Items</td>
</tr>
<tr>
<td>Total Expenditure</td>
</tr>
</tbody>
</table>

37. Within our non-staff costs there are three areas where the underspends are more than £5,000 and these are:

a. Travel and Subsistence costs (£7k) below budget because inspection levels are low in the first quarter compared to the profiled budget.

b. Conference and project costs (£17k), the budget was profiled for the Annual conference to take place in June, as it had last year. The actual spend to date is £4k resulting in a variance of (£9k). Costs relating to Business Planning and Conference Attendance are underspent by (£7k) again a result of budget profiling.

c. Consultancy costs (£5k) which cover cost of staff surveys and the expenditure has been profiled in the first quarter, however the actual costs are likely to be incurred in the autumn if not Q4. An amendment to this profile will be made in Q2.

d. Non-cash costs (£14k) which relate to the depreciation/amortisation of our fixed assets; assets which we had budgeted to be deployed from April 2018 (CRM upgrade and new laptops) are yet to be released as a result year to date expenditure has been lower than budgeted.

38. The remaining variances are smaller and range from £3k for postage, printing and stationery to £4k underspend within IT and Telecommunications.
Other key performance indicators

Debtors

39. As at 30 June 2018 our outstanding debts total £334k represented by 25 organisations of which 2 are from 2017/18 business year and total £4k. We billed establishments within the Human Application sector this year a total of £1,427k represented by 139 organisations. The outstanding debt from this cycle is £330k (24%).

40. The two accounts outstanding from 2017/18 are two organisations that were paying in instalments and have now gone into liquidation. We do not anticipate receiving the remaining monies.

41. Below is a breakdown by sector of the outstanding debts as at 30 June 2018.

<table>
<thead>
<tr>
<th>Sector</th>
<th>Number of establishments</th>
<th>Value of %ge debt £</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS</td>
<td>9</td>
<td>76,653.75</td>
</tr>
<tr>
<td>Government Bodies</td>
<td>4</td>
<td>162,350.46</td>
</tr>
<tr>
<td>Non Government Bodies</td>
<td>12</td>
<td>91,314.17</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
<td>330,318.38</td>
</tr>
</tbody>
</table>

42. The Government Bodies value is represented by monies due from DHSC (£12k) for a seconded employee; two Arm’s Length Bodies (NHS Resolution and HFEA £87k) and the Welsh Government (£63k). All are expected to pay within the next few weeks.

Forecast Outturn

43. A forecast exercise has been undertaken following a review of Q1 expenditure, this has focused on our more significant costs, mainly staff and travel costs. Below is a summary forecast outturn. The table shows a more or less break even position, with a small surplus against budget of £14k.
44. We are forecasting a small increase in our income against budget. This assumes that the second billing round of sectors in September generates £2,214k and that we receive all of our rental and seconded staff income.

45. Of our costs, we have made assumptions that a number of vacant posts will not be filled before the start of Q3 (October 2018).

46. A number of pressures have been identified, and some funds may be available for key areas such as recruitment, interim staff appointments and training, both corporate and career investment scheme. It may be necessary to defer any decision on additional funds for training until Q3 when we would have more certainty on the potential surplus available.

**Financial risks**

47. Financial risks are monitored on an on-going basis. Below is a table of the current key risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high-level strategic risks that SMT has identified and is managing. The strategic risk five – insufficient, or ineffective management of financial resources – is currently rag status yellow as we have a challenging budget due a small decline in licence fee income. As of Q1, we are forecasting a small overspend.

### Table Four: Forecast Outturn

**Summary - Income & Expenditure**

**For the Three Months Ending 30 June 2018**

<table>
<thead>
<tr>
<th>INCOME &amp; EXPENDITURE SUMMARY</th>
<th>Forecast</th>
<th>Budget</th>
<th>Variance</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td>(4,859,285)</td>
<td>(4,853,588)</td>
<td>(5,697)</td>
<td>0.12%</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>4,856,744</td>
<td>4,836,835</td>
<td>19,909</td>
<td>0.41%</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(2,541)</td>
<td>(16,753)</td>
<td>14,212</td>
<td>-84.83%</td>
</tr>
</tbody>
</table>
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**

48. In April and May we continued work towards GDPR compliance and achieved our stated aim of creating a defensible position by 25 May. Work continues beyond this date to further improve upon this position.

49. We have developed a specification for a Managed IT Support Service and will be publishing this on the Crown Commercial Services Technology Services 2 framework in Q2.

50. We have made some improvements to the resilience of our on-premise data centre by purchasing an additional backup power supply. The new power supply is now supporting the server infrastructure and the old power supply will be moved over to support the networking and communications infrastructure in Q2.

**Working environment**

51. Following feedback from an all staff away day we are considering ways to improve the working environment, namely through improvements to video and audio conferencing facilities.

**Deployment KPI narrative**

**Performance against 2018/19 KPIs**

52. KPI 11 Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly) was marked as red, at 24% in March.

53. All other Delivery KPIs for quarter one are within target or tolerance and marked as green.
Audit and Risk Assurance Committee Update

Purpose of paper

1. To provide an overview of the work of the Audit and Risk Assurance Committee (ARAC) over the last year.

Decision-making to date

2. None.

Action required

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

Background

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

5. Membership of ARAC through the past year has been:
   - Amanda Gibbon (ARAC Chair);
   - Stuart Dollow (Authority Member);
   - Glenn Houston (Authority Member);
   - Bill Horne (Authority Member);
   - Andy Hall (Authority Member)
6. ARAC met three times in 2017/18. The Chief Executive, the Director of Resources, the Head of Finance and Governance, the HTA’s external and internal auditors and a representative of the Department of Health and Social care (DHSC) attended all meetings. Other Directors and staff attended to discuss particular risk areas that the ARAC wished to explore, or other topics depending on the ARAC’s business.

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

Role and function

8. ARAC’s formal role is to advise the Accounting Officer and Authority on:
   • the strategic processes for risk, control and governance and the Annual Governance Statement;
   • the accounting policies, the accounts, and the annual reports of the HTA, levels of error identified, and management’s letter of representation to external auditors;
   • the planned activity and results of both internal and external audit;
   • adequacy of management response to issues identified by audit activity, including external audit’s audit completion report;
   • assurance relating to corporate governance requirements for the HTA; and
   • policies on whistle-blowing and fraud prevention, including the arrangements therein for special investigations.

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

Review of Committee effectiveness

10. The Committee reviewed its effectiveness in the period March 2017 to March 2018. This consisted of members responding to a series of questions relevant to ARAC at this time, as set out in the National Audit Office Audit and Risk Assurance Committee effectiveness checklist. The questions cover themes such as:
   • What does ARAC do for the Authority?
   • Does the annual cycle of business cover all that we should?
   • Do ARAC papers cover what is needed? If not, what would be better?
   • Do we have sufficient expertise on the committee and in internal/external audit attendees properly to scrutinise as we should?
   • Do we have sufficient time in meetings?
• Are the training sessions valuable? If you feel you need more training, what would that cover?
• Do you feel able to raise everything you would like to discuss?
• Is there anything we could do better?

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

12. ARAC members attended the DHSC and National Audit Office (NAO) events, including networking meetings of audit committee members.

Risk management

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

14. The Committee discusses in some detail the revisions to the HTA’s risk register, with a particular focus on appetite and tolerance of risk and the need to consider risk interdependency with the DHSC and the wider network of the Department’s arm’s length bodies. The Committee approved a revised version of the HTA risk policy at its February 2018 meeting.

15. During the year, the Committee also identified risk areas to explore in greater detail and relevant staff attended Committee meetings to provide more information and assurance on:
   • Human Application sector; and
   • Cyber security.

Information and cyber security

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

17. The HTA takes its responsibility for information and cyber security seriously. As such, this area occupies a significant proportion of the ARAC’s time. During this period the ARAC has received regular reports on the HTA response to IT and cyber incidents during the period, compliance with the new General Data Protection Regulation (GDPR) as well as overall data and cyber security.

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

19. Throughout the year, no data losses were identified and the SIRO considered that information risk was managed adequately. The management and the Committee have requested that our Internal Auditor undertake a review of the HTA’s approach to cyber security during the 2018/19 financial year.

Internal audit

20. During this period, the HTA appointed the Government Internal Audit Agency as HTA’s Internal Auditor from 1 April 2017. The Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress. In total four audits were undertaken across cyber security, corporate governance of risk management, our approach to achieving GDPR compliance and our financial control regime.

21. There were three high priority findings during the year, all relating to the cyber security audit. The opinion given on our financial controls audit was substantial assurance (the highest rating). The Committee concluded that management has responded positively to audit findings and recommendations and has taken, or is in the process of taking, action to implement agreed recommendations from Internal Audit Reports.

22. The Internal Auditor gave “moderate” assurance that the HTA had adequate and effective systems of control, governance and risk management in place for the reporting year 2017/18. A rating of moderate demonstrates that an organisation has a good standard of assurance.

23. The Committee reviewed and approved an audit plan for the upcoming financial year.

External audit

24. NAO officials attended all Committee meetings and continued to make a valuable contribution to discussions. The NAO recommended an unqualified opinion on the 2017/18 accounts and agreed that the Governance Statement complies with HM Treasury guidelines.

Assurance processes

25. During 2017/18, the Chief Executive usually met with HTA Directors every week (individually) to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors met weekly to approve policies, review exceptions, identify and act on lessons learned.
26. The Committee believes that ongoing management review and communication, supported by the findings of audits and Departmental oversight gives sufficient evidence to provide the Accounting Officer with assurance that the systems are sufficiently robust, and that the exceptions are relatively insignificant.

Governance statement

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

Summary

28. The HTA’s governance systems are well established and there is a commitment to making continuous improvements to them. The Committee is satisfied with the HTAs arrangements for risk management and its assurance processes.
Transplantation Advisory Group Update

Purpose of paper

1. To update the Authority on the key points discussed at the Transplantation Advisory Group (TAG) meeting held on 23 May 2018.

Decision-making to date

2. None.

Action required

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

Background

4. Two substantive topics were discussed in detail: these were the project on sustainability of the Independent Assessor (IA) system and the increase in living donor transplantation in the private sector.
IA Sustainability project

5. Five themes for action have been identified following feedback from the sector and HTA team discussions. These are:

- Recruitment of Independent Assessors (IAs)
- Payment/reimbursement of expenses
- Reaccreditation
- Training
- Governance arrangements

6. The proposals identified under each of these categories were agreed and work to fully scope out the project will begin in July, once the Transplant Manager returns to her post following period of secondment. A key discussion point was the importance of recognition of the IA role at Board level within Trusts / Health Boards.

Private transplantation

7. The Group discussed living donor transplantation in the private sector, which has increased, particularly in the past year. This increase in referrals has largely come from clinical teams working in private wings of NHS hospitals, rather than private hospitals. Overseas patients make up the largest proportion of these donor and recipient pairs. All of these cases have been directed donations, with the exception of three, which were directed altruistic donations.

8. On occasion, these cases have been more difficult to assess and have taken longer to review; this is for a variety of complex reasons.

- Reimbursement – In private cases recipients often directly reimburse the donor’s expenses, this can include loss of earnings, flights, accommodation and subsistence whilst in the UK. Reimbursement often takes place outside the strict parameters of the NHS reimbursement scheme. This makes it more difficult for the Panel to judge what is fair and reasonable and to rule out reward.

- There is also usually little or no living donor coordinator involvement; this means that there is sometimes a lack of separation between the clinical teams caring for the donor and recipient.

9. There are examples of good private sector practice and there is a lot of guidance to draw from. It was agreed that the HTA would meet with one of the private hospitals to understand how they address these complex challenges and understand the processes more thoroughly in order to decide next steps.
Opt out consent for organ donation in England

10. The Group was updated on the Government’s plans to introduce a system of opt out consent for deceased organ donation in England. The Government response to its consultation is expected to be published in July.

Closing remarks

11. The Group extended their warmest thanks and gratitude to Keith Rigg, as this was his last meeting. Keith was a founding member of the Group in 2006. Alun Williams will replace Keith as a member of TAG.

12. Next TAG meeting will be held on 4 October 2018.
Histopathology Working Group Update

Purpose of paper

1. To make Authority Members aware of current issues in the post mortem sector, as discussed at HWG on 19th June 2018. Current areas of concern are the:

   ● level of regulatory compliance
   ● shortage of pathologists to carry our coroners’ post mortems.

Decision-making to date

2. None.

Action required

3. The Authority should support the steps proposed by the staff to deal with apparent deterioration in compliance in this sector.

4. The Authority should consider whether there are any supportive actions that we wish to take regarding the shortfall of pathologists to undertake coroners’ post mortems.

Background

5. Unfortunately, this meeting clashed with an Audit and Risk Assurance Committee meeting (ARAC), but we were able to ensure adequate representation from staff and Authority Members. It was agreed that the governance team would ensure that future committee scheduling would avoid such clashes.
Regulatory compliance

6. There are three types of data, which provide an overall picture of compliance in the post-mortem sector: analysis of HTA reportable incidents (HTARIs), self-assessment compliance reports, and shortfalls in inspections.

7. The total number of incident reports to HTA increased from 180 in 2016-17 to 237 in 2017-18. However, these numbers include near-miss events (11 in 2017-18) and incidents judged not to fall within HTA’s remit e.g. damage to a body outside of the mortuary (62 in 2017-18). The numbers of actual HTARI incidents remain stable. The single biggest category is damage to body (46 reports in 2017-18).

8. It was agreed that HWG should receive, at each meeting, a rolling trend analysis of actual, near miss and non-Reportable Incident events, with a ‘deep dive’ every one to two years, depending on numbers and trends.

9. Self-reports of compliance are by their nature limited in scope, and to some extent subjective, but emerging concerns are:

   • levels of staff in mortuaries, along with a tendency to employ unqualified mortuary assistants instead of mortuary technicians;
   • equipment and premises.

10. It was agreed that future questionnaires should increase the focus on verifiable data (e.g. number and grade of staff), rather than matters of opinion, as this will increase their validity as a source for recommendations.

11. Inspection shortfalls gave great cause for concern. There has been an increase in both the number and severity of shortfalls, with approximately 60 per cent of inspections now showing major shortfalls. Again, recurrent themes are staffing and premises/equipment, along with audit and traceability, possibly related to low staffing. It would be unwise to attribute these additional shortfalls solely to recent changes in Codes and Standards.

12. In response to these overall trends, four areas of work are planned:

   • Using all data for each site, develop a risk-based inspection model for the sector
   • Develop guidance documents for high risk areas of work
   • Train inspectors to ensure consistency in deciding shortfalls
   • Develop a process for escalation both internally and at the hospital where a site shows repeated shortfalls or non-responsiveness to them.
13. It was agreed that we need further analysis to (1) see whether staffing levels and shortfalls correlate (2) examine whether the definitions of shortfalls are always realistic e.g. the level of identification available at coroners’ post mortems.

14. It was also agreed that, in collaboration with the Royal College of Pathologists (RCPPath) and the Association of Anatomical Pathology Technicians, we should organise a training day for DIs in this sector. Training of coroners’ officers should also include sessions with the HTA, and vice versa for new HTA staff.

**Shortage of pathologists to undertake coroners’ post mortems**

15. Currently, in excess of 95 per cent of post mortems in the UK are mandated by coroners. These are undertaken by histopathologists employed by hospitals whose main activity is diagnostic work for the living. Their post mortem work for coroners sits outside the NHS, being ultimately accountable to the Ministry of Justice, and is separately remunerated on an item of service basis. The numbers of pathologists willing to undertake post mortems is falling, and the pressure of diagnostic work on pathologists will not decrease in the immediate future. HWG reviewed a survey undertaken by the Coroners Society on availability of pathologists. The findings concur with a similar survey undertaken by the RCPPath.

16. Key findings are:

- Adequate numbers of trainee histopathologists are undertaking post mortem training, but insufficient numbers of them go on to work in post mortem practice as a consultant.
- The independence of pathologists performing coroners’ post mortems is valued and should be maintained, but the possibility of recognising this work within consultant job plans should be investigated. However, the appetite for bringing this work into the NHS will be limited unless sufficient funding is provided.
- The current level of remuneration (less than £100 per post mortem) is wholly inadequate to cover the time taken and needs to be increased. This fee is statutory and any increase would require legislative change.

17. Possible mitigations include:

- Centralisation of coroners’ post mortems, with necessary movement of bodies
- Increased use of post mortem imaging. Guidance is being produced jointly by RCPPath and the Royal College of Radiologists. Colleagues are advised however, that whilst this technology will resolve ‘simple’ causes of death, complex cases will still require internal examination of the body. These will take more time per case and thus exacerbate the shortfall in remuneration. Post mortem imaging is not currently a regulated activity.
Introduction of Medical Examiners (MEs)

18. Jeremy Hunt has recently announced that MEs will be introduced in April 2019, initially covering deaths in acute hospitals only. In contrast to the initial proposals, MEs will be employed by hospitals for this work, thus lessening their independence (and therefore perhaps making it more important that coroners’ post mortems remain outside the NHS). Whilst this progress is very welcome, there is concern as to whether/when other sectors will also be covered.

19. Funding will come from current cremation fees, but additional funding will be required. There is no further detail at present, other than confirmation that the National Medical Examiner post will be reinstated, which is also welcome. The Royal College of Pathologists (RCPPath), as lead College, has developed a job description and person specification, along with guidance for appraisal and revalidation of MEs. RCPPath Council is considering possible ways in which the College could support MEs through training and/or affiliation. The impact of MEs on the number of coroners’ post mortems is unclear; data from pilot sites were contradictory. It may be that there will be fewer coroners’ post mortems overall, but those, which are undertaken, will be of greater complexity.

Issues for next HWG meeting

20. We will focus on fetal and neonatal deaths, with outcomes from the ‘Death Before Birth’ project, and the possible move of stillbirth investigation from the NHS to the Ministry of Justice.
Report on the outcomes of our regulation and the impact for patient safety and public confidence

Purpose of paper

1. To provide the Authority with an overview of the assurance measures used by the HTA in regulating licensed establishments during the 2017/18 business year.

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

Decision-making to date

3. This report was approved by the CEO on 12 July 2018 for submission to the Authority.

Action required

4. The Authority is asked to note the content of this paper and to consider the data presented at the meeting in light of the aims set out in paragraph 7.

Background

5. As part of the 2017/18 business planning process, the Authority requested that a Delivery Key Performance Indicator (KPI) be developed to give the Authority assurance in relation to HTA activities aimed at ensuring human tissue is used safely.
Aims of a safety KPI

6. The purpose of this (KPI) is to capture and demonstrate, using robust evidence, the positive impact that the HTA has in this area. As such, it can serve as an assessment of the effectiveness of the regulatory methods we employ and the extent to which they influence our sectors.

7. The overall aims of the annual report are to:
   a. Provide assurance to the Authority on the effectiveness of our regulation and the impact the HTA has on the safe use of human tissue
   b. Develop a strong evidence basis to better understand key areas of non-compliance risk in each sector
   c. Provide recommendations for improvement and inform strategic decisions based on the identified areas of risk and opportunities, aiming to promote the safe use of tissue through regulatory compliance
   d. Improve resource management through the better targeting of regulatory action and better utilisation of shared learning
   e. Provide assurance to SMT and the Authority that we are aware of, and prepared for, future opportunities and challenges

Wider outcomes of the report

8. The report will not replace periodic publications, such as the sector-specific review reports. Generating the report however, has provided a focus for compiling a more comprehensive standard data set for each sector.

9. We have created advanced finds in CRM, alongside standard Excel templates for data analysis. These are stored centrally and so can be accessed by colleagues across the organisation. This allows a single source of data to be used across projects. Examples of where this has already been applied for the 2017/18 data set include the annual review report and for reporting against the 2017/18 Business Impact Target.

10. The report can also be a useful, evidence-based tool to inform HTA strategy and identify key areas for policy development. As such, a full copy of the report will be provided in advance of the Authority’s annual Strategic Planning Away Day in September 2018.
HTA Policy for managing and referring potential criminal breaches of Human Tissue legislation

Purpose of paper

1. To seek the Authority’s approval of the HTA’s Policy for managing and referring potential criminal breaches of Human Tissue legislation.

Decision-making to date

2. SMT reviewed the content of this paper and the policy and approved them for submission to the Authority at its meeting on 12 July.

Action required

3. The Authority is asked to approve the proposed policy for managing and referring potential criminal breaches of Human Tissue legislation in Annex A.

Background

4. The HTA keeps all of its policies under regular review in light of experience. In most cases the revisions are approved by the Executive. In the case of this policy, the Authority retains responsibility for formal approval of any revisions. The Authority approved the policy that is currently in use at its meeting on 9 February 2017.

5. Since May 2017, the Authority has been provided with details of all police referral decisions as part of the quarterly Delivery report along with its rationale for each decision.
6. The referral decisions that have been taken by SMT since the policy was last approved are summarised in the table below.

**SMT police referral decisions since February 2017**

<table>
<thead>
<tr>
<th>Sector</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/17</td>
<td>ODT</td>
</tr>
<tr>
<td></td>
<td>A European Union (EU) Competent Authority in another Member State made us aware of a website, which appeared to offer a British matching donor service in exchange for a fee. This was referred to the police who in turn referred this on to the country in which the company offering the service is registered.</td>
</tr>
<tr>
<td>03/17</td>
<td>PM</td>
</tr>
<tr>
<td></td>
<td>An establishment notified us that relevant material had been removed from the body of a deceased person on unlicensed premises. SMT concluded that the HTA should not refer the establishment to the police for investigation.</td>
</tr>
<tr>
<td>04/17</td>
<td>HA</td>
</tr>
<tr>
<td></td>
<td>An investigation was conducted into the procurement of adipose tissue by two licensed establishments and the export / import to / from a European Institute, where appropriate authorisation and licences were not in place for this work. The MHRA was contacted about the issue and investigated the matter separately. SMT concluded that the HTA should not refer either establishment to the police for investigation. (See Investigation 05/17)</td>
</tr>
<tr>
<td>05/17</td>
<td>HA</td>
</tr>
<tr>
<td></td>
<td>Concerns were raised about an establishment that had undertaken distribution and export of adipose tissue without formal authorisation from the HTA. SMT concluded that the HTA should not refer the establishment to the police for investigation.</td>
</tr>
<tr>
<td>06/17</td>
<td>PM</td>
</tr>
<tr>
<td></td>
<td>An establishment notified us that relevant material had been removed during a PM examination without appropriate consent. SMT concluded that the HTA should not refer the establishment to the police for investigation.</td>
</tr>
<tr>
<td>01/18</td>
<td>HA</td>
</tr>
<tr>
<td></td>
<td>Import of corneas by a surgeon for clinical use to a number of premises without an HTA licence for import. SMT concluded that the HTA should not refer the establishment to the police for investigation.</td>
</tr>
</tbody>
</table>

7. SMT also reviews the policy after each decision to assess whether it presented any weaknesses or limitations in allowing the decision to be made. From SMT’s perspective, the policy, and in particular the indicative factors approach, remains fit for purpose.

**Recommendation**

8. On the basis of SMT’s experience of using the policy, it does not propose any amendments and recommends that the policy continues to apply in its current form.
Policy for managing and referring potential criminal breaches of Human Tissue legislation

Aim

1. This policy is primarily intended to assist HTA decision makers in reaching a view on whether or not to refer an apparent criminal breach of Human Tissue legislation to the police for investigation.

Purpose

2. This policy sets out how the HTA decides whether to refer apparent breaches of Human Tissue legislation to the police where those breaches may amount to criminal offences.

3. When we refer to Human Tissue legislation we mean:

   a) the Human Tissue Act 2004 (“the Act”),
   b) the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (“the 2007 Regulations”), and
c) the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (“the 2012 Regulations”)
4. The criminal offences under the Act and the Regulations are set out in Appendix 1.

Background

5. Human tissue legislation sets out the activities that have the potential to become criminal offences if they are not undertaken lawfully. Specifically, some activities are made lawful:

- when appropriate consent is in place;
- under the authority of a licence from the HTA;
- through the HTA disapplying a legal prohibition e.g. living organ donation;
- through HTA powers to issue Directions e.g. non-consensual DNA analysis.

Other activities will remain unlawful under any circumstances; trafficking in transplantable material being an example. The offences created by human tissue legislation are included in Appendix 1.

6. In undertaking its statutory functions, the HTA has a number of mechanisms by which it can identify breaches of legislation. The HTA has statutory power to carry out inspections and investigations, including the power to enter premises and seize documents. In some situations, regulatory action may be sufficient to deter or avoid any potential criminal breach of Human Tissue legislation.

7. In the course of its regulatory activity the HTA may uncover evidence suggesting offences may have been committed under Human Tissue legislation or other legislation e.g. human trafficking offences. This policy only relates to referral to the police in circumstances where the police would not, other than by the actions of the HTA, be informed that an offence appeared to have been committed.

8. This policy relates only to the management and referral of potential offences committed in England, Wales and Northern Ireland. Where the HTA identifies potential offences carried out in Scotland, police referral will be made via the appropriate Scottish Government officials.

Legal Considerations relevant to the HTA’s role

9. Although the Authority’s licensing role and its regulatory powers are clearly defined in human tissue legislation, the scope of the Authority’s role in relation to investigating and prosecuting offences is not expressly set out. Accordingly, the

---

1 The HTA may identify potential offences committed in Scotland in its role as UK Competent Authority under European legislation. It may also identify offences in the course of making living donation assessments, which the HTA undertakes under contract to the Scottish Government.
Authority has to determine what its role should be. In making that decision, the following factors have been taken into account.

- A person duly authorised by the Authority and by signed warrant has power to search any premises (not only licensed premises) where there are reasonable grounds to believe that an offence is being or has been committed. Such a duly authorised person also has the power to seize anything that he or she has reasonable grounds to believe may be required as evidence in proceedings for an offence. This suggests that the Authority may have a role to play in gathering evidence to support investigation of a potential criminal offence referred to the police by either the HTA or other parties.
- The Authority is given no express power under the Act to conduct interviews under caution. Although the absence of an express power does not prevent members of staff of the Authority conducting interviews under caution, the Authority takes the view that the absence of express provisions in the legislation points against assuming that role in relation to criminal investigations.
- The Act contains legal requirements and offences that the HTA has no regulatory power to enforce, and which it may never come across through its regulatory activities, such as those relating to the non-consensual analysis of DNA.

10. Some of the offences under the Act require the consent of the Director of Public Prosecutions (“the DPP”) in order to prosecute. For practical reasons, the involvement of the Crown Prosecution Service (CPS) would be required in relation to such offences.

11. Taking all these factors into account, and in view of the HTA’s lack of expertise to investigate, interview or gather evidence to a standard that would be required for criminal prosecution, the HTA has determined that its policy will be to refer potential breaches of human tissue legislation to the appropriate police force for investigation, where this is indicated. The HTA will use its limited powers of investigation to assist the police where this is required. The police force will undertake liaison with the CPS.

12. In making a decision about referral to the police for investigation, the HTA considers the impact that any offence, and its severity, has on patient safety (see indicative factors in para 28). The CPS, in deciding whether or not to bring a prosecution, will consider whether doing so is in the public interest. As a result, it is at the discretion of the CPS whether or not to bring a prosecution in a situation where there is evidence of an offence having been committed under human tissue legislation. This position is consistent with the HTA’s duty to superintend compliance with its founding legislation (see para 13).
13. This policy will be supported by a protocol to be agreed with the National Police Chiefs’ Council (NPCC).

Principles

Discharge of responsibilities

14. The Authority’s functions as set out in section 15 of the Act include superintending, in relation to activities within its remit, compliance with requirements of Parts I and II of the Act. Establishing an agreed process whereby offences under the Act are referred to the police for investigation contributes to the discharge by the Authority of its duties under the Act. The Authority must exercise its discretion to refer to the police for investigation in a rational and reasoned way.

15. Even where there is evidence of a criminal offence, the Authority retains discretion not to refer a case for investigation by the police, for example in the circumstances described in paragraph 22. However, the manner in which that discretion is exercised is crucial. As a public body, the Authority’s decisions are subject to scrutiny by means of Judicial Review to consider whether the Authority’s discretionary powers have been exercised irrationally or without consideration of relevant factors or after taking into account irrelevant factors. Decision-making, therefore, needs to be properly reasoned and documented. A decision not to refer may be revisited if circumstances suggest that further review is appropriate.

Consistency

16. There is also a need for the Authority’s decision making to be consistent. This does not mean, however, that the Authority should decide to refer every case in which there is an alleged criminal breach of a particular section of the Act or Regulations to the police. The HTA strives to achieve consistency by articulating and reasoning decisions using a list of indicative factors.

17. In adopting this ‘indicative factors’ approach for decisions on whether to refer a case to the police for investigation and potential prosecution under the Act, or Regulations, lists of factors have been established which may point in favour of or against referral.

18. The absence of relevant evidence should not necessarily be a reason, which prevents the Authority from making a referral as, in many cases, the referral to
the police will be for the purpose of investigating whether there is evidence of an offence.

**HTA decision making process**

19. The HTA’s decision making framework sets out the principles of decision making within the HTA and the delegation of decision making for possible police referrals.

**Notification of potential offence**

20. The Authority may receive notification of a potential offence from a number of sources including:

- intelligence gained from someone in an establishment or in the sector
- inspection processes
- notification from a member of the public
- notification by the police
- notification from another body such as another regulator or a research ethics committee

**The role of the Director of Regulation**

21. The Director of Regulation has responsibility for oversight of all potential criminal cases, which relate to offences under human tissue legislation. Under the schedule of delegation for decision making, decisions on referral to the police are taken by SMT.

22. When information is received to the effect that a criminal offence may have been committed this will be managed initially by the Director of Regulation through the HTA’s regulatory processes, where it is possible to do so. The aim of this is to seek to establish the facts of the case and to gather enough information to reach a decision about whether the activity identified appears to be a criminal offence, and/or one, which can be managed using regulatory tools. The Director of Regulation will inform the CEO of the potential criminal offence at the earliest opportunity.

23. The Director of Regulation has delegated responsibility for making the judgement as to whether the evidence of the case indicates that an offence may have been committed taking into account all of the information available. The Director of Regulation is responsible for deciding the timing of referral of the case to SMT for decision but will inform SMT of progress of the HTA’s investigation and the reasons for any delay in referring a case.
24. The Director of Regulation’s conclusions and decision with respect to delegated cases must be recorded. If a clear breach of the Act or the Regulations has been identified, the establishment concerned should normally be informed that the breach has been noted and that it will form part of the establishment’s licensing history when considering the need for regulatory action on any future occasion.

25. In exceptional circumstances where urgent referral to the police may be required, either to protect public safety, or where there is a concern that a delay may result in evidence that may be relevant to a criminal proceeding being compromised, the Director of Regulation may, with reference to the Chief Executive or other Director if the Chief Executive is unavailable, make the referral to the police directly without an SMT decision.

**The Senior Management Team**

26. The Senior Management Team must be quorate to make a decision on police referral. A legal adviser and the appropriate Head of Regulation may also be present to offer advice if required.

27. The Senior Management Team will consider the information available by reference to the indicative factors set out below. SMT may defer making a decision until additional evidence is gathered. In the case of a potential organ trafficking offence, which has come to light through the living donation assessment process, the referral would not usually be made until the right to reconsideration of the Authority’s original decision had been exhausted.

28. Where a decision is made, a record should be made of this in the SMT minutes, whether it is to refer the case to the police or not, and the reasons for it. The Chair will be informed of the decision as soon as possible and a report made to the Authority at the next practicable Authority meeting.

**Indicative factors in deciding whether to refer to the police**

**Factors in favour of referral**

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

   a) The alleged offence poses a risk to public safety
   b) The alleged offence has the potential to damage public confidence in the use of human tissue
c) Referral to the police for investigation would have a positive impact on maintaining public and/or professional confidence in the use of human tissue
d) A person committing the alleged offence concerned is or was in a position of authority or trust, for example a licence holder or designated individual
e) A person committing the alleged offence was a ringleader or an organiser of the events
f) The alleged offence may have been deliberate or that steps have been taken to conceal the facts related to the alleged offence or to mislead anyone concerning the facts related to the alleged offence (including the falsification of any information in any document or delay in reporting the activity which may constitute an offence)
g) The alleged offence or other offences under human tissue legislation are likely to be continued or repeated, for example, by a history of recurring conduct
h) The alleged offence was committed despite a warning being given that the conduct may amount to an offence or that a licence was required
i) The alleged offence continued over a significant period of time
j) The information indicating the alleged offence is assessed to be reliable

Factors against referral

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

a) The alleged offence poses no risk to public safety
b) The alleged offence has limited potential to damage public confidence in the use of human tissue
c) A person committing the alleged offence has already been subject to criminal proceedings relating to the specific events in the UK or abroad
d) A person committing the alleged offence concerned acknowledged the breach of human tissue legislation to the Authority and/or the person concerned has not attempted to conceal the matter
e) The alleged offence related to an isolated incident, which is unlikely to be repeated, for example as a result of regulatory action or changes in governance arrangements at the establishment
f) It appears that committing the alleged offence was not a deliberate act and occurred as a result of a genuine mistake or misunderstanding
g) There has been a long delay since the alleged offence occurred
h) The information indicating the alleged offence is assessed to be unreliable

A reasoned approach
31. A referral will usually take place when the Senior Management Team is satisfied that the public interest factors in favour of referral outweigh those tending against.

**Recording decisions**

32. Any decision made by the Senior Management Team must be recorded. The record of the decision should include a summary of the available information, the decision of SMT and the reasons for the decision, by reference to the factors.

**Process for referral to the police**

33. SMT will delegate responsibility for making the police referral to the appropriate Head who will liaise with the Home Office to identify the appropriate point of contact within the relevant police force. The referral will consist of:

a) a summary of the alleged offence
b) where the offence relates to a regulatory matter, a regulatory investigation report signed by the Chief Executive
c) where the offence relates to a regulatory matter, details of any regulatory action taken by the HTA
d) a chronology of events
e) a checklist of all retained documents, with confirmation this is subject to any legal requirements for privacy and data protection.
f) where it is required, the HTA impact assessment
g) whether this case has also been notified to the CPS

34. Where urgent referral to the police may be required, either to protect public safety, or where there is a concern that a delay may result in evidence that may be relevant to a criminal proceeding being compromised, the referral may be made orally with the full paperwork provided subsequently.

35. Where the offence relates to a service being provided to the public and that service may be disrupted as a result of a referral, the HTA will conduct an impact assessment in line with its Decision Making Framework. This will inform stakeholder engagement to minimise disruption to service delivery and maintain public confidence. The HTA will update this impact assessment on a fortnightly basis, and send a further copy to the police after every review.

36. Section 5 (consent), section 32 (commercial dealings in transplantation) and section 33 (restrictions on living organ donation) of the HTAct 2004 include offences that require the consent of the DPP for prosecution. Where the HTA becomes aware of this type of alleged offence, the HTA will alert the CPS in
each of these cases at the same time a referral is made to the police. Given that there will be few opportunities for individual police forces to develop any expertise in relation to Human Tissue legislation; the HTA will ensure that at the time of any such referral, the Special Crime Division of the Crown Prosecution Service is notified.

37. During an investigation, the police may require formal statements from HTA members of staff or other types of information. These will be requested through the appropriate Head at the HTA.

38. The police may also require expert evidence from the HTA. Where such a request is made, the police and HTA will rely on the Guidance Booklet for Experts (see related documents).

Related documents

<table>
<thead>
<tr>
<th>Document</th>
<th>Date</th>
</tr>
</thead>
</table>
### Revision history

<table>
<thead>
<tr>
<th>Date</th>
<th>Version</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>16 August 2011</td>
<td>0.1</td>
<td>For SMT review on 18 August 2011</td>
</tr>
<tr>
<td>13 September 2011</td>
<td>0.2</td>
<td>Incorporating SMT comments</td>
</tr>
<tr>
<td>21 February 2012</td>
<td>0.3</td>
<td>Redraft to incorporate elements of HTA/POL/023</td>
</tr>
<tr>
<td>23 February 2012</td>
<td>1.0</td>
<td>Version agreed by SMT</td>
</tr>
<tr>
<td>8 April 2014</td>
<td>2.0</td>
<td>Revised version amended by AMS in light of the legal advice provided by Mills and Reeve (21 November 2013)</td>
</tr>
<tr>
<td>28 January 2014</td>
<td>2.1</td>
<td>Revised in light of regulatory action relating to establishment operating without a licence</td>
</tr>
<tr>
<td>26 February 2015</td>
<td>15.0</td>
<td>Version ratified following police referral decision on 26 February. New version numbering scheme adopted</td>
</tr>
<tr>
<td>3 August 2016</td>
<td>16.0</td>
<td>Fundamental review of the policy to provide greater clarity on the HTA role in investigation and as a basis for beginning discussion with NPCC following the disbanding of ACPO.</td>
</tr>
<tr>
<td>7 October 2016</td>
<td>16.1</td>
<td>Revised in light of comments from SMT, Heads and Authority Member Bill Horne and Chair Sharmila Nebhrajani.</td>
</tr>
<tr>
<td>9 February 2017</td>
<td>17.0</td>
<td>Revised in light on comments received from Members on 1 November 2016 and in subsequent correspondence.</td>
</tr>
<tr>
<td>19 July 2018</td>
<td>18.0</td>
<td>Version reviewed at the Authority meeting on 19 July 2018.</td>
</tr>
</tbody>
</table>
Appendix 1

Offences under the Human Tissue Act 2004

1. Various offences are created by the Human Tissue Act, 2004 (the Act). A summary of the offences is provided below.

a) Consent

- Section 5(1): Prohibition of Activities without consent;
- Section 5(2): Making of a false representation in relation to activities requiring consent;
- Section 5(3): Storage of body for use for anatomical examination without the relevant signed certificate;
- Section 5(5): Use of body for anatomical examination without the death of the person being registered; and
- Section 8(1): Restriction of activities in relation to donated material.

b) Licensing

- Section 25(1): Breach of licence requirement unless there is a reasonable belief that the activity is not a licensable activity or that the individual acts under the authority of a licence;
- Schedule 5 Paragraph 8 Enforcement Offences: failure without reasonable excuse to comply with Paragraph 1(1) (Production of Statutory Records for Inspection) or Paragraph 6(3) (Inspector’s Supplementary Powers) or intentional obstruction of the exercise of an inspector’s rights under Schedule 5 (see Schedule 2 paragraph 1 for further explanation).

c) Anatomical specimens

- Section 30: Possession of anatomical specimens away from licensed premises, subject to exceptions (see Schedule 2 paragraph 2 for further explanation);
- Section 31: Possession of former anatomical specimens away from licensed premises (see Schedule 2 paragraph 3 for further explanation).

d) Trafficking / Transplantations

- Section 32: Prohibition of commercial dealings in human material for transplantation (see Schedule 2 paragraph 4 for further explanation);
- Section 33: Restriction on transplants involving live donors (see Schedule 2 paragraph 5 for further explanation);
Section 34(3): Failure to comply with the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006 in relation to the supply of information about transplant operations or knowingly or recklessly supplying information, which is false or misleading in a material respect.

e) DNA analysis

Section 45: Non-consensual analysis of DNA, subject to exceptions (see Schedule 2 paragraph 6 for further explanation)

2. It is important to note that proceedings for offences under Sections 5, 32 or 33 of the Act (see above) may not be instituted except by or with the consent of the DPP (or in the case of Northern Ireland, the DPP for Northern Ireland).

3. Section 49 of the Act envisages the prosecution of individuals and corporate bodies. Section 49(1) provides that where an offence under the HT Act is committed by a body corporate and is proved to have been committed with the consent or the connivance of or to be attributable to any neglect on the part of:

   a) any director, manager, secretary or other similar officer of the body corporate, or
   b) any person who was purporting to act in such capacity,

he (in addition to the body corporate) commits the offence and will be liable for prosecution.

4. An offence can also be committed by neglect.

Offences under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

5. In addition to offences created by the Act, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the 2007 Regulations) create offences, which are summarised below. Offences under the 2007 Regulations may be committed by a person, body corporate or Scottish partnership.

   • breach of requirement to hold a licence or to act under a third party agreement;
   • breach of confidentiality requirement; and
   • enforcement offences.
Offences under the Quality and Safety of Organs Intended for Transplantation Regulations 2012

6. Offences under the 2012 Regulations may be committed by a person or body corporate.

- Undertaking organ procurement activities (donor characterisation; organ characterisation; preservation of an organ; making arrangements to transport an organ; or retrieval of an organ) without a licence.
- Undertaking organ transplantation activities (organ characterisation; preservation of an organ; making arrangements to transport an organ; or implantation of an organ) without a licence.