Sixty-first Meeting of the Human Tissue Authority

Date 28 May 2013
Time 10.00 – 1.00
Venue The Westminster Conference Centre
1 Victoria Street
London
SW1H 0ET

Agenda (I) = for information; (D) = for decision

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Welcome and apologies</td>
</tr>
<tr>
<td>2.</td>
<td>Declarations of interest</td>
</tr>
<tr>
<td>3.</td>
<td>Minutes of 18 March 2013 HTA (22/13)</td>
</tr>
<tr>
<td>4.</td>
<td>Matters arising</td>
</tr>
<tr>
<td>5.</td>
<td>Chair’s report</td>
</tr>
<tr>
<td>6.</td>
<td>Independent review of HTA and HFEA (I) HTA (23/13)</td>
</tr>
<tr>
<td>7.</td>
<td>HTA Staff Survey Results (I) HTA (24/13)</td>
</tr>
<tr>
<td>8.</td>
<td>HTA Code of Practice on the donation of organs for transplantation after death in Wales (D) HTA (25/13)</td>
</tr>
<tr>
<td>10.</td>
<td>Reporting of serious incidents to the HTA (I) HTA (27/13)</td>
</tr>
<tr>
<td>11.</td>
<td>Independent Assessor Survey Results (I) HTA (28/13)</td>
</tr>
<tr>
<td>12.</td>
<td>Regulatory Activity Report Q4 (I) HTA (29/13)</td>
</tr>
<tr>
<td>13.</td>
<td>Living Donation Activity Report Q4 (I) HTA (30/13)</td>
</tr>
<tr>
<td>15.</td>
<td>Authority scrutiny of risk register (I) HTA (32/13)</td>
</tr>
<tr>
<td>16.</td>
<td>Strategic Performance Review April 2013 (I) HTA (33/13)</td>
</tr>
<tr>
<td>17.</td>
<td>Any other business</td>
</tr>
</tbody>
</table>
Minutes of the sixtieth meeting of the Human Tissue Authority

Date 18 March 2013
Venue Westminster Conference Centre
1 Victoria Street
London
SW1H 0ET

<table>
<thead>
<tr>
<th>Present</th>
<th>In attendance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Members</strong></td>
<td><strong>In attendance</strong></td>
</tr>
<tr>
<td>Baroness Diana Warwick (Chair)</td>
<td>Mrs Sarah Bedwell (Director of Regulation)</td>
</tr>
<tr>
<td>Mrs Jodi Berg</td>
<td>Dr Alan Clamp (Chief Executive)</td>
</tr>
<tr>
<td>Mr Brian Coulter</td>
<td>Mrs Sue Gallone (Director of Resources)</td>
</tr>
<tr>
<td>Professor Susan Dilly</td>
<td>Dr Shaun Griffin (Director of Communications and Public Affairs)</td>
</tr>
<tr>
<td>Mrs Rosie Glazebrook</td>
<td>Ms Elvira Manjaji (Regulation Manager)</td>
</tr>
<tr>
<td>Mrs Pamela Goldberg</td>
<td>Mr Allan Marriott-Smith (Director of Strategy and Quality)</td>
</tr>
<tr>
<td>Mrs Suzanne McCarthy</td>
<td>Mrs Victoria Marshment (Authority Secretary)</td>
</tr>
<tr>
<td>Professor Gurch Randhawa</td>
<td></td>
</tr>
<tr>
<td>Mr Keith Rigg</td>
<td></td>
</tr>
<tr>
<td>Ms Catharine Seddon</td>
<td></td>
</tr>
</tbody>
</table>

**Observers**

Mr Patrick Irwin (Department of Health)
Mr Ted Webb (Department of Health)
<table>
<thead>
<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
</tr>
</thead>
</table>
| Item 1 | Welcome and apologies                      | 1. Baroness Warwick welcomed Members and observers to the sixtieth meeting of the Human Tissue Authority (HTA).  
2. Apologies had been received from Professor Michael Banner. |
| Item 2 | Declarations of interest                   | 3. There were no declarations of interest.                              |
| Item 3 | Minutes of 22 January 2013 [paper: HTA (10/13)] | 4. The minutes of 22 January were adopted with one amendment.  
5. The action under item 9 on the complaints report should read “For the complaints policy to be amended to reflect that a report would be considered by the Authority every six months.”  
**Action:** For the minutes of 22 January 2013 meeting to be amended to state that the complaints report would be considered every six months. |
| Item 4 | Matters arising                            | 6. A note addressing matters arising was circulated to Members on 12 March.  
7. A note had been circulated to all staff on 5 March thanking them for their hard work on the successful implementation of the EU Organ Donation Directive.  
8. The next complaints report would be an agenda item at the September Authority meeting.  
9. In future the complaints report would be an agenda item at the March and September Authority meetings.  
10. The HTA’s standing orders were updated to reflect the decision-making framework as presented at the January Authority meeting. The updated standing orders had been sent to the Department of Health (DH) and published on the HTA’s website.  
11. The strategic risk register had been updated to remove references to the EU Organ Donation Directive and the Living Organ Donation Framework. |
| Item 5 | Chair’s report                             | 12. There had been a series of meetings with Justin                     |
McCracken regarding the review of the HTA’s and Human Fertilisation and Embryology Authority’s (HFEA) respective functions.

13. Headline feedback from the stakeholder interviews which had been conducted as part of the review had been shared.

14. The HTA ran an organisation-wide Leadership and Business Planning Day on 11 February. The morning session was led by Alan Clamp and focused on the ways in which all HTA staff could improve their leadership skills. Diana Warwick attended the afternoon session which reviewed the developing business plans for 2013/14 and at which staff of all grades had the opportunity to present.

15. The HTA ran an extremely successful conference as part of the SOHO V&S project (Substances of Human Origin, Vigilance and Surveillance) between 18 to 20 February. It was noted that the case studies presented by other countries highlighted the potential consequences when due vigilance was not routine and consistent.

16. There had not yet been any formal notification from DH on the reappointment of the four Members whose terms of appointment finish at the end of March. DH had informed the HTA that a decision on the appointment of an additional professional Member would not be taken until Justin McCracken’s review was completed.

17. Information on the meetings attended by the Chair, Chief Executive and members of the Senior Management Team (SMT) was included in the paper supporting item 14 on the agenda.

**Item 6 Independent review of HTA and HFEA [paper: HTA(11/13)]**

18. Alan Clamp introduced the paper which gave an overview of the review of the HTA and HFEA which DH had commissioned Justin McCracken to undertake.

19. The Authority had not met since the announcement on 25 January that the HTA and HFEA would not be merged into the Care Quality Commission (CQC) and that an independent review would be undertaken.

20. The independent review’s terms of reference cover streamlining the way the HTA and HFEA undertake their functions, the options for a reduction in the burden of regulation, and the scope for a merger of the two bodies.
21. The report is scheduled to be published in late April. It is expected that the draft recommendations would be shared with the HTA in mid-April.

22. Justin McCracken had provided a note on the themes which had emerged from his interviews with stakeholders. These were:
   a. Public confidence in the sensitive areas regulated by the HTA is now high. Specialist expertise and focus in the regulator are key elements in maintaining this.
   b. The burden of regulation is the biggest issue for those stakeholders interviewed so far.
   c. Recognition that the HTA takes a positive approach to listening to stakeholders’ views, and to change.
   d. The HTA’s agreement with the Human Research Authority (HRA) is seen as good practice.
   e. Progress in developing closer cooperation with other regulators is recognised, and more could be done in this regard.
   f. Concerns were expressed from the bioscience sector about the complexity created by the two separate regimes of the HTA and the Medicines and Healthcare products Regulatory Agency (MHRA). Joint inspections were welcomed as step in the right direction, but a seamless regulatory pathway is needed to facilitate the development of cell based therapies.
   g. Eliminating overlaps with Clinical Pathology Accreditation (CPA) inspections is seen as important.
   h. Evidence that understanding among stakeholders of the HTA’s approach to regulation and the way this is developing is uneven, and a more structured approach to engagement on this issue might be beneficial.
   i. Support was articulated for further reductions in cost.
   j. HTA fees should be more transparent and predictable and consideration should be given to establishing a standing industry liaison group.
   k. Mixed views were expressed about the concept of merger.

23. The review would consider a range of potential merger options to realise further efficiencies, the uniting theme of these being the co-location of the two bodies.

24. Members noted that The Mid Staffordshire NHS Foundation Trust Public Enquiry Report recommended...
that there should not be any unnecessary organisational change within the health sector. Effective regulation and patient confidence and protection should be a priority.

25. The Authority recalled that in 2006/7 Parliament had considered the merits of merging the HTA and HFEA to form the Regulatory Authority for Tissues and Embryos (RATE). At that time the view had been that this would not lead to effective regulation.

26. There was discussion as to the level of actual savings which could be made, as the HTA’s non-licence fee income is relatively low at £770k per annum. The Authority was advised that the potential savings identified by the review were indicative at this stage, and would require further analysis.

27. Members expressed concern at the continued uncertainty for the staff of the HTA and the potential impact on attrition and retention figures, which had been much improved over the previous year.

28. It was noted that there may be greater efficiencies to be gained by collaborations with bodies other than, or in addition to, the HFEA and the review’s terms of reference were somewhat limiting.

29. Members shared their experiences of mergers in both the public and private sectors and noted that, more often than not, the envisaged savings had not been realised.

30. It was stressed that while a focus on reducing regulatory burden was important, the protection of patients and the public should be the priority.

31. Colleagues from DH reinforced the point that the review was independent of Government.

32. Members stated that it was imperative for the HTA to maintain its commitment to making further efficiencies and increasing collaboration.

33. Members noted that under any proposal there must be certainty that the HTA’s core functions continue to be delivered effectively and with public confidence. Any merger must lead to better, or at the very least equivalent, standards of regulation.

34. It was agreed that the Chief Executive would summarise the points made by Members to form the basis of an HTA submission to the review, which would be approved by the Chair on behalf of the Authority.

35. The Authority noted the content of the paper.

Action: For the Chief Executive to draft an HTA
<table>
<thead>
<tr>
<th>Item 7</th>
<th>HTA Code of Practice on the donation of organs for transplantation after death in Wales [paper: HTA(12/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>36.</td>
<td>Allan Marriott-Smith introduced the paper and informed Members that the Minister for Health and Social Care at the Welsh Government had committed to a Code of Practice being available for the end of May when she gave evidence to the Health and Social Care Committee on 10 February.</td>
</tr>
<tr>
<td>37.</td>
<td>SMT and the Chair made the decision that the benefits of the HTA committing (on a best endeavours basis) to providing a draft Code of Practice by this date outweighed the risks.</td>
</tr>
<tr>
<td>38.</td>
<td>The HTA had made clear to the Welsh Government that the Code of Practice would be an HTA document, and, where consensus cannot be reached by mid-May, minority views would be represented by annotations to the main body of the text.</td>
</tr>
<tr>
<td>39.</td>
<td>Members would have opportunity to review the working document during the period 11-25 April, and the near final draft at the meeting on 28 May.</td>
</tr>
<tr>
<td>40.</td>
<td>External legal input would be sought, as well as that of an ethicist.</td>
</tr>
<tr>
<td>41.</td>
<td>The Code of Practice would be subject to public consultation later in the calendar year.</td>
</tr>
<tr>
<td>42.</td>
<td>Members noted that the Health Minister of the Northern Ireland Assembly had committed to consulting on the introduction of an opt-out system for deceased organ donation. This should be considered when drafting the Code of Practice to ensure that, as far as possible, the high level regulatory principles in regard to an opt-out system are clearly defined to support the policy development elsewhere in the UK.</td>
</tr>
<tr>
<td>43.</td>
<td>The Authority noted the content of the paper.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 8</th>
<th>Paired kidney exchange with the Republic of Ireland [paper: HTA(13/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>44.</td>
<td>Allan Marriott-Smith introduced the paper which provided an overview of arrangements currently in-place for donor and recipient pairs from the Republic of Ireland to enter the UK living kidney sharing schemes.</td>
</tr>
<tr>
<td>45.</td>
<td>At present a donor and recipient pair are admitted to the</td>
</tr>
<tr>
<td>Item 9</td>
<td>Report of the Audit Committee meeting 7 February 2013 [paper: HTA(14/13)]</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Catharine Seddon introduced the item and gave an update on the Audit Committee meeting of 7 February.</td>
</tr>
<tr>
<td></td>
<td>It had been agreed with the internal auditors that their focus for the rest of the year would be on efficiencies, rather than transition.</td>
</tr>
<tr>
<td></td>
<td>There would be a National Audit Office (NAO) facilitated workshop on self-assessment of performance for members of the Audit Committee.</td>
</tr>
<tr>
<td></td>
<td>It had been agreed that the level of reserves would be reviewed by the Committee in six months’ time.</td>
</tr>
<tr>
<td></td>
<td>No changes had been made to the Audit Committee Handbook.</td>
</tr>
<tr>
<td></td>
<td>It was noted by the Committee that SMT’s commitment to a culture of openness had been commended by the NAO. This allowed the Committee to have confidence in</td>
</tr>
<tr>
<td>Item 10</td>
<td>Authority scrutiny of risk register [paper: HTA(15/13)]</td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>57. The Authority noted the content of the paper and approved the Audit Committee Handbook.</td>
<td></td>
</tr>
<tr>
<td>58. Sue Gallone introduced the paper and gave an update on the strategic risk register.</td>
<td></td>
</tr>
<tr>
<td>59. During SMT's most recent review of the register it was agreed that the risk relating to relationship management had not yet changed, but SMT was live to the potential impact of the independent review of the HTA and HFEA as well as the production of a Code of Practice on deemed consent in Wales.</td>
<td></td>
</tr>
<tr>
<td>60. Members asked that a note be added to the strategic risk register key to differentiate between amber and yellow risk ratings.</td>
<td></td>
</tr>
<tr>
<td>61. The Authority noted the content of the paper.</td>
<td></td>
</tr>
<tr>
<td><strong>Action:</strong> For a note be added to the key of the strategic risk register to differentiate between amber and yellow risk ratings.</td>
<td>SGa</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 11</th>
<th>Strategic plan 2013 to 2016 [paper: HTA(16/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>62. Allan Marriott-Smith introduced the paper and the draft strategic plan 2013-16 document.</td>
<td></td>
</tr>
<tr>
<td>63. The plan would be published on the HTA’s website on 2 April, subject to final input from Members.</td>
<td></td>
</tr>
<tr>
<td>64. It was agreed that high-level information should be included on the committee structure of the HTA. This would provide further assurance on the mechanisms in place to meet strategic aim four on governance and management.</td>
<td></td>
</tr>
<tr>
<td>65. The Authority noted the content of the report and approved publication with the addition of committee information.</td>
<td></td>
</tr>
<tr>
<td><strong>Action:</strong> For high-level information on the committees of the HTA to be included in the final strategic plan 2013-16.</td>
<td>AMS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 12</th>
<th>Regulatory Activity Report Q3 [paper: HTA(17/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>66. Sarah Bedwell introduced the report which had been discussed at the Policy and Regulatory Activity Group meeting of 12 March.</td>
<td></td>
</tr>
<tr>
<td>67. There had been a successful mediation process.</td>
<td></td>
</tr>
</tbody>
</table>
undertaken with a licensed establishment which in the first instance had failed to comply with Directions issued on the processing and storage of stem cells.

68. A review of the mediation process would be undertaken to establish whether this could become a standard step when escalation of non-compliance is required.

69. It was confirmed that the HTA had not needed to employ external mediators, and as such the costs incurred were low.

70. A paper on Serious Untoward Incidents (SUIs) and Serious Adverse Events and Reactions (SAEARs) would be brought to the May Authority meeting to consider in more detail the rise in the number of SUIs and the reasons for this.

71. It was noted that when unreported SUIs are identified by a Regulation Manager on inspection, the establishment is now required to report these, which may in part have contributed to the increase.

72. It was agreed that the paper on SUIs and SAEAR would include a trend analysis, the results of which would be communicated to the relevant sectors.

73. The Authority noted the content of the report.

**Action:** For a paper on SUIs and SAEARs to be bought to the May Authority meeting.

<table>
<thead>
<tr>
<th>Item 13</th>
<th>Living Donation Activity Report Q3 [paper: HTA(18/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>74. Allan Marriott-Smith introduced the report which had been discussed at the Policy and Regulatory Activity Group meeting on 12 March.</td>
<td></td>
</tr>
<tr>
<td>75. There had been an increase in the number of living organ donation cases received by the HTA, compared to the corresponding quarter of the previous year.</td>
<td></td>
</tr>
<tr>
<td>76. The percentage of cases which required panel consideration had also increased.</td>
<td></td>
</tr>
<tr>
<td>77. A paper on the options for interviewing donors and recipients based in different parts of the UK would be brought to the Authority in due course.</td>
<td></td>
</tr>
<tr>
<td>78. There were plans to establish a private living lung donation programme at a UK hospital. The HTA had provided information of the requirements under the Human Tissue Act 2004 and associated Regulations.</td>
<td></td>
</tr>
<tr>
<td>79. The HTA had confirmed to a television production company that Independent Assessments could not be filmed.</td>
<td></td>
</tr>
</tbody>
</table>
80. The Authority noted the content of the report.

<table>
<thead>
<tr>
<th>Item 14</th>
<th>Communications Evaluation Report Q3 [paper: HTA(19/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>81. Shaun Griffin introduced the report which was the first in this format and would become a regular quarterly agenda item.</td>
<td></td>
</tr>
<tr>
<td>82. The responses to the Arms’ Length Bodies review consultation had been overwhelmingly positive about the HTA. Of the 109 responses, only 7 were negative towards the HTA or supported the proposed transfer to the CQC.</td>
<td></td>
</tr>
<tr>
<td>83. Steps were being taken to ensure greater granularity in enquiry logging processes and the subsequent reporting.</td>
<td></td>
</tr>
<tr>
<td>84. The Authority noted the content of the report.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 15</th>
<th>Strategic Performance Review February 2013 [paper: HTA(20/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>85. Allan Marriott-Smith introduced the paper which updated Members on the progress against Key Performance Indicators.</td>
<td></td>
</tr>
<tr>
<td>86. Members noted the low attrition and vacancy rates and congratulated SMT on these.</td>
<td></td>
</tr>
<tr>
<td>87. The Authority noted the content of the report.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 16</th>
<th>Finance Report February 2013 [paper: HTA(21/13)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>88. Sue Gallone introduced the paper which provided Members with the financial position as at end February 2013.</td>
<td></td>
</tr>
<tr>
<td>89. The forecasted overspend would be smaller than expected, at approximately £600k. The overspend this year was due to re-payment of reserves to DH and the subsidy of fees for the organ donation and transplantation sector, which had been met from HTA reserves.</td>
<td></td>
</tr>
<tr>
<td>90. In real terms, this meant that the HTA would spend around £200k less than expected during 2012-13. As this is a relatively small amount, the HTA would not credit establishments with unused fees this year.</td>
<td></td>
</tr>
<tr>
<td>91. The Authority noted the content of the report.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Item 17</th>
<th>Any other business</th>
</tr>
</thead>
<tbody>
<tr>
<td>92. A panel of three Authority Members had reconsidered a living organ donation case on 15 March. A review of the process and procedures supporting reconsiderations of</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>this nature would be undertaken to refine and improve systems, where necessary.</td>
<td>93. Work had been undertaken on the action the HTA would be required to undertake to ensure it was fully compliant with the recommendations of The Mid Staffordshire NHS Foundation Trust Public Enquiry Report.</td>
</tr>
<tr>
<td>The meeting closed at 12.15pm</td>
<td></td>
</tr>
</tbody>
</table>
Authority paper

Date 28 May 2013 Paper reference HTA (23/13)
Agenda item 6 Author Alan Clamp

Independent review of HTA and HFEA

Purpose of paper

1. This paper aims to provide the Authority with an update on the independent review of the HTA and the HFEA undertaken by Justin McCracken.

Action

2. Members are asked to note the content of the paper.

Decision-making process to date

3. SMT approved this paper for the Authority at its meeting on 16 May.

Background

4. Between June and September 2012, the Department of Health, consulted on the proposed transfer of functions from the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA), to the Care Quality Commission (CQC) and Health Research Authority (HRA).

5. In response to the consultation, the Department of Health announced in January 2013 its intention to maintain the HFEA and HTA as statutory bodies for the time being. At the same time it commissioned an independent review of the way in which the HFEA and HTA undertake their functions and operations, with a view to delivering greater efficiencies and giving serious consideration to
a merger of the two bodies. The review was undertaken by Justin McCracken between January and April 2013.

Current position

6. The independent review report was submitted to the Public Health Minister and Minister for the Cabinet Office in April 2013.

7. We understand that the government’s response to the report will be published alongside the report itself. At present there is no firm indication of when this will be.
HTA Staff Survey Results

Purpose of paper

1. The purpose of this paper is to provide the Authority with a summary of the results of the HTA Staff Survey which was undertaken during February 2013, together with a draft action plan to address areas for improvement identified by the survey.

Action

2. The Authority is asked to note the content of the paper and provide any comments.

Decision-making process to date

3. The 2012/13 business plan included a staff survey to be undertaken towards the end of the business year.

4. SMT decided to use Capita as the survey provider as they had done a successful job at a reasonable cost on the 2011 survey and there were no other procurement requirements. In order to be able to compare with the 2011 survey the vast majority of questions were unchanged, although some further questions were added to improve the usefulness of feedback.

5. The high-level results of the survey were discussed at a SMT meeting and an all staff meeting during March 2013. At its meeting on 9 May, the SMT approved this paper for the Authority.
Background

6. The HTA undertakes a survey of all staff approximately once every 18 months to gather feedback about all aspects of our operations in order to make improvements to working practices.

7. The previous staff survey was undertaken in 2011 and reported a generally positive picture of the organisation. A number of areas for improvement were identified and an action plan was drawn up and monitored by the Staff Forum. All the key actions arising from this survey were completed by the end of 2012.

Survey results 2013

8. The main findings of the 2013 survey were as follows:

- The response rate was 87% (40 out of 46 staff), which was identical to the 2011 survey.

- Overall survey outcomes improved since 2011 and were very good.

- There were no significant deteriorations since 2011 and there was a significant improvement in scores in 14 areas. These included: views on SMT (+28%), feeling valued by the HTA (+19%), learning and development (+19%), managing change (+17%) and communications (+16%).

- When compared to other similar organisations, the HTA scored significantly higher for: SMT lead the organisation well (+23%), effective internal communications (+23%), appraisal undertaken in the last 12 months (+19%), delivering a good quality service (+14%) and feeling proud to work for the HTA (+10%). The HTA scored significantly lower for the current level of learning and development (-8%).

- There was a large number of questions across a range of areas that scored highly for the HTA and just one question that received a low score identifying it as a key area for improvement – many respondents were not satisfied that their salary is fair for their role.

Staff Survey Action Plan (SSAP)
9. Despite there being no significant deteriorations in scores since 2011 and only one key area for improvement identified, staff at the HTA are committed to using the survey findings to make further improvements. Therefore all responses indicating a dissatisfaction rating of 15% or more have been included in the SSAP for 2013/14 (see Annexe A).

10. The SSAP identifies a number of areas for improvement, as shown in Annexe A, but these can be summarised into four key areas:

- Additional guidance on line management, including standardised (but flexible) agendas for 1:1 meetings.
- Establishing a working group to look at ways to further improve the performance management and development processes.
- Addressing the four questions where scores have declined (not statistically significant) since 2011. These are highlighted in Annexe A.
- The Remuneration Committee to meet in June 2013 to discuss the job evaluation exercise and pay remit for 2013/14.
### HTA Staff Survey Action Plan 2013-14 [DRAFT]

<table>
<thead>
<tr>
<th>Survey Finding</th>
<th>Action(s)</th>
<th>Owner(s)</th>
<th>Completion Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.3 My work is varied and interesting to me [15% disagree].</td>
<td>All line managers to discuss with staff in Q1 and facilitate changes where possible.</td>
<td>Line managers.</td>
<td>30 June 2013</td>
<td>Declined since 2011 survey [was 6%].</td>
</tr>
<tr>
<td>2.5 I feel valued by the HTA [21% disagree].</td>
<td>All staff to identify what is required in order to feel valued and to share this with the Staff Forum or suggestions box.</td>
<td>All staff. Staff Forum (to make recommendations to SMT).</td>
<td>30 June 2013</td>
<td>Improved since 2011 [was 39%].</td>
</tr>
<tr>
<td>2.6 I feel my job security at the HTA is good [23% disagree].</td>
<td>SMT to provide realistic reassurances about job security based on the independent review, ongoing financial constraints and political imperatives.</td>
<td>SMT.</td>
<td>Following publication of the independent review and government response.</td>
<td>Unchanged since 2011 [was 25%].</td>
</tr>
<tr>
<td>4.3 SMT set out a clear vision of where the HTA is headed [15% disagree].</td>
<td>SMT to clarify and reinforce strategic objectives and key business priorities with all staff.</td>
<td>SMT.</td>
<td>Following publication of the independent review and government response.</td>
<td>Improved since 2011 [was 33%].</td>
</tr>
<tr>
<td>5.2 I am satisfied with my current role and level of responsibility [33% disagree].</td>
<td>Line managers to discuss with all staff in Q1, looking at job roles, internal opportunities and professional development (including the CIS) to</td>
<td>Line managers.</td>
<td>30 June 2013.</td>
<td>Unchanged since 2011 [was 36%].</td>
</tr>
<tr>
<td>5.6</td>
<td>I feel that too many approvals are needed for routine decisions [48% agree].</td>
<td>Line managers to review decision-making with all staff to ensure there is no unnecessary bureaucracy. AMS to clarify governance processes with all staff at the May Staff Meeting.</td>
<td>Line managers. AMS.</td>
<td>31 May 2013.</td>
</tr>
<tr>
<td>6.3</td>
<td>My line manager gives me recognition for work done well [18% disagree].</td>
<td>Line managers to provide more feedback to staff through regular, structured 1:1 meetings and in writing each quarter (in addition to review meetings at mid-year and end-year).</td>
<td>Staff Forum to agree a (flexible) model 1:1 agenda – to include feedback. Line managers to provide (and all staff to expect) written recognition of work done well each quarter.</td>
<td>31 July 2013</td>
</tr>
<tr>
<td>6.4</td>
<td>My line manager provides me with feedback about my performance [15% disagree].</td>
<td>Line managers to provide more feedback to staff through regular, structured 1:1 meetings and in writing each quarter (in addition to review meetings at mid-year and end-year).</td>
<td>Line managers to provide more feedback to staff through regular, structured 1:1 meetings and in writing each quarter (in addition to review meetings at mid-year and end-year).</td>
<td>31 July 2013</td>
</tr>
<tr>
<td>6.5</td>
<td>My line manager helps to motivate me to give my best [34% disagree].</td>
<td>In addition to improved feedback, all staff to identify what is required in order to feel valued and to share this with the Staff Forum or suggestions box.</td>
<td>All staff. Staff Forum (to make recommendations to SMT).</td>
<td>30 June 2013</td>
</tr>
<tr>
<td>Section</td>
<td>Question</td>
<td>Action</td>
<td>Target Date</td>
<td>Notes</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>-----------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td>6.10</td>
<td>My line manager understands the technical aspects of my work [15% disagree].</td>
<td>All line managers to discuss with staff in Q1 to identify the importance of this understanding and actions to address the issue.</td>
<td>Line managers. 30 June 2013</td>
<td>Improved since 2011 [was 21%].</td>
</tr>
<tr>
<td>7.3</td>
<td>Did the performance review leave you feeling your work is valued by the HTA [25% said no]?</td>
<td>[See actions relating to 2.5] PDP process to be reviewed to address this issue and that in 7.5, seeking views from the Staff Forum. Revisions to the process to be implemented prior to the mid-year review period.</td>
<td>AC to lead discussions and propose changes to the PDP process. DP to implement changes in September 2013. 30 September 2013</td>
<td>Improved since 2011 [was 48%].</td>
</tr>
<tr>
<td>7.5</td>
<td>Do you feel the PDP process improves your individual performance [67% said no]?</td>
<td>PDP process to be reviewed to address this issue and that in 7.3, seeking views from the Staff Forum. Revisions to the process to be implemented prior to the mid-year review period.</td>
<td>AC to lead discussions and propose changes to the PDP process. DP to implement changes in September 2013. 30 September 2013</td>
<td>N/A (new question for 2013)</td>
</tr>
<tr>
<td>7.6</td>
<td>Have you received the training, learning and development identified in the PDP development plan [29% said no]?</td>
<td>Line managers to check with all staff about CPD needs not addressed in 12/13 and prioritise these for 13/14. Mid-year review to be used to check that all CPD needs have been addressed.</td>
<td>Line managers and DP. 31 May 2013.</td>
<td>Unchanged since 2011 [was 27%].</td>
</tr>
<tr>
<td>Question</td>
<td>Action</td>
<td>Date</td>
<td>Notes</td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>------------</td>
<td>--------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>7.7 Do you feel that the learning and development opportunities available help to improve your individual performance [28% said no]?</td>
<td>Line managers to discuss with all staff in Q1 of 13/14 and development plans reviewed and amended. DP to survey staff in Q1 to evaluate the quality and impact of training events in 12/13.</td>
<td>30 June 2013</td>
<td>N/A (new question for 2013).</td>
<td></td>
</tr>
<tr>
<td>8.1 Overall, I feel the HTA offers a good pay and reward package [36% disagree].</td>
<td>RemCo meeting in June 2013 to review the pay remit and job evaluation exercise. Outcomes to be discussed with staff at the following staff meeting. DP to provide all staff with a benefits statement. DP and SGa to further investigate options for non-pay benefits.</td>
<td>30 June 2013</td>
<td>Improved since 2011 [was 43%].</td>
<td></td>
</tr>
<tr>
<td>8.2 I am satisfied that my salary is fair for my role [50% disagree].</td>
<td>N/A (new question for 2013).</td>
<td>N/A (new question for 2013).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.3 I feel that the HTA offers good non-pay benefits [38% disagree].</td>
<td>N/A (new question for 2013).</td>
<td>N/A (new question for 2013).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.3 Relationships at work are strained [15% agree].</td>
<td>All staff to identify possible causes of strained relationships (and actions</td>
<td>30 June 2013</td>
<td>Declined since 2011 survey [was 8%].</td>
<td></td>
</tr>
<tr>
<td>Section</td>
<td>Survey Question</td>
<td>Recommended Action</td>
<td>Responsible Party</td>
<td>Date of Action</td>
</tr>
<tr>
<td>---------</td>
<td>----------------</td>
<td>--------------------</td>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>9.4 I am required to do unimportant tasks which prevent me completing more important ones [30% agree].</td>
<td>Line managers to review with all staff in Q1 to identify these unimportant tasks and minimise their occurrence and impact.</td>
<td>Line managers</td>
<td>30 June 2013</td>
<td>Unchanged since 2011 [was 33%].</td>
</tr>
<tr>
<td>9.5 Overall I feel unduly stressed at work [15% said yes].</td>
<td>Line managers to review with all staff in Q1 to identify the causes of undue stress and minimise their impact. DP to review opportunities to manage stress via wellbeing initiatives and CPD.</td>
<td>Line managers and DP.</td>
<td>30 June 2013</td>
<td>Unchanged since 2011 [was 13%].</td>
</tr>
<tr>
<td>11.6 Communication between senior management and staff is effective [20% disagree].</td>
<td>Use line manager discussions, Staff Forum and suggestions box to seek ideas for ways to improve two-way communication. SMT to review communication of key messages to staff.</td>
<td>All staff.</td>
<td>30 June 2013</td>
<td>Improved since 2011 [was 31%].</td>
</tr>
<tr>
<td>Number</td>
<td>Description</td>
<td>Action</td>
<td>Status</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>----------------------</td>
<td></td>
</tr>
<tr>
<td>11.7</td>
<td>I feel well briefed on what happens in SMT discussions [28% disagree].</td>
<td>[See 11.6]</td>
<td>[See 11.6]</td>
<td></td>
</tr>
<tr>
<td>11.8</td>
<td>There are effective channels for staff to feed their views upwards in the HTA [15% disagree].</td>
<td>[See 11.6]</td>
<td>[See 11.6]</td>
<td></td>
</tr>
<tr>
<td>11.9</td>
<td>I feel my voice is heard on issues of significance to the organisation [24% disagree].</td>
<td>[See 11.6]</td>
<td>[See 11.6]</td>
<td></td>
</tr>
<tr>
<td>12.1</td>
<td>I am confident my ideas or suggestions will be listen to [18% disagree].</td>
<td>[See 11.6]</td>
<td>Ongoing</td>
<td></td>
</tr>
<tr>
<td>12.2</td>
<td>I am confident I will get feedback on my ideas and suggestions [18% disagree].</td>
<td>[See 12.1]</td>
<td>Ongoing</td>
<td></td>
</tr>
<tr>
<td>13.1</td>
<td>Overall learning and development has helped me to do my job more effectively [31% disagree].</td>
<td>[See 7.7]</td>
<td>Improved since 2011 [was 44%].</td>
<td></td>
</tr>
<tr>
<td>13.2</td>
<td>I feel that I am given the same opportunities to Line managers to discuss with all staff in Q1 and</td>
<td>Line managers (and DP).</td>
<td>30 June 2013</td>
<td>Improved since 2011 [was 29%].</td>
</tr>
</tbody>
</table>
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

<table>
<thead>
<tr>
<th>13.3 I am satisfied with my current level of learning and development [34% disagree].</th>
<th>[See 7.7 and 13.2]</th>
<th>[See 7.7 and 13.2]</th>
<th>[See 7.7 and 13.2]</th>
<th>Improved since 2011 [was 48%].</th>
</tr>
</thead>
<tbody>
<tr>
<td>13.4 I feel that the HTA offers learning and development opportunities that assist with my career development [24% disagree].</td>
<td>[See 5.2]</td>
<td>[See 5.2]</td>
<td>[See 5.2]</td>
<td>N/A [new question for 2013].</td>
</tr>
<tr>
<td>14.1 I am actively seeking to leave the employment of the HTA [36% agree].</td>
<td>All staff to identify possible causes of turnover (and actions for address these) and to share this with line managers, the Staff Forum or suggestions box.</td>
<td>All staff and Staff Forum (also to consider reasons given in the survey in section 14.2 of the survey).</td>
<td>30 June 2013.</td>
<td>Unchanged since 2011 [was 38%].</td>
</tr>
<tr>
<td>15.2 There is too much local change for change sake [26% agree].</td>
<td>All line managers to review proposed changes for necessity and impact. All changes implemented to be explained and monitored to ensure that anticipated benefits are realised.</td>
<td>Line managers.</td>
<td>Ongoing.</td>
<td>Improved since 2011 [was 42%].</td>
</tr>
<tr>
<td>15.3 I think things will improve in the next 12 months [18% disagree].</td>
<td>SMT to provide realistic reassurances about job</td>
<td>SMT, Staff Forum.</td>
<td>30 September 2013.</td>
<td>Improved since 2011 [was 40%].</td>
</tr>
</tbody>
</table>
months [34% disagree].

| Security and the future of the HTA based on the independent review, ongoing financial constraints and political imperatives. Staff Survey Action Plan to be agreed by all staff and closely monitored by the Staff Forum to ensure improvements. AMS to lead on organisational quality improvement initiatives. | Verbatim comments | Improvements required to be reviewed as a priority by the Staff Forum and any additional actions identified and added to this plan. | Staff Forum | 31 May 2013 | N/A. |
Authority paper

Draft HTA Code of Practice on living and deceased organ and tissue donation for transplantation – Wales

Purpose of paper

1. To provide the Authority with the working draft of the HTA Code of Practice on living and deceased organ and tissue donation for transplantation – Wales.

2. To seek comments from Members on the content of the draft Code of Practice.

Action

3. Members are asked to provide comments on the draft Code of Practice and sign-off the document in principle.

Decision-making process to date

4. A paper outlining the decision to agree to draft a Code of Practice for the Human Transplantation (Wales) Bill 2013 at short notice was discussed at the March 2013 Authority meeting.

5. At the meeting the Authority endorsed the decision made by the Chair and Executive.

Background

6. The HTA agreed earlier this year to seek to provide the Welsh Minister for Health and Social Care with a draft Code of Practice to support the final stages of scrutiny of the Human Transplantation (Wales) Bill 2013.
7. A first draft was shared with Authority Members, colleagues at the Welsh Government, Morgan Cole LLP, two ethicists and a small number of NHS Blood and Transplant (NHSBT) colleagues in mid-April.

8. A second draft was shared with Authority Members and colleagues at the Welsh Government and NHSBT in early-May. Members were also provided with the opportunity to provide comments on the draft at the Policy and Regulatory Activity Group (PRAG) on 14 May.

9. This draft reflects (as far as possible) the comments received on the second draft.

**Next steps**

10. If this draft is approved in principle by the Authority, final amendments will be made on 29 May, prior to SMT undertaking a final review on 30 May. The draft Code of Practice will be made available to the Welsh Minister on 31 May.

11. If the draft is not approved in principle, a revised timeline for delivery will be agreed with the Welsh Minister.

12. The draft Code of Practice will be made available on the HTA website, with an explanatory note making it clear that this version is not yet in effect, nor is it the version which will be consulted on later in the year. The version published for consultation will need to reflect the legislation as passed.

13. The next phase of this project will begin once (and if) the legislation receives Royal Assent. The Welsh Government hopes this will be in August this year. Following Royal Assent, the Code of Practice will need to be updated to reflect the legislation as passed. This draft will then be brought to the Authority for approval, prior to a 12 week period of public consultation.
Note

This document is a draft Code of Practice and as such is liable to change before the public consultation which is expected to take place in autumn 2013.

This document has been produced to support the final stages of scrutiny of the Human Transplantation (Wales) Bill.

This document is not to be used operationally.

If you have any questions please contact the Human Tissue Authority on enquiries@hta.gov.uk.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

HTA Code of Practice on living and deceased organ and tissue donation for transplantation - Wales
Contents

Purpose of this Code of Practice ................................................................. 4
Authority under which this Code of Practice is produced ................................... 5
The role of the Human Tissue Authority .................................................................... 6
Overview ................................................................................................................... 7
Information on the terminology used in this Code of Practice ........................................ 8
Other documents which provide advice and guidance in this area ................................... 9
Who can seek consent ............................................................................................ 10
Qualifying relationships ......................................................................................... 11
Legislative frameworks ............................................................................................. 13
Types of organ donation after death ........................................................................ 15
Transplantation activities .......................................................................................... 16
Relevant material ....................................................................................................... 17
Novel transplants ....................................................................................................... 18
Organs which are not listed on the Organ Donor Register ........................................ 19
Deemed consent and express consent ....................................................................... 20
Establishing whether deemed consent applies ......................................................... 22
Establishing whether a person made a decision during life ........................................ 31
Evidence which would satisfy a reasonable person that the person would not have given
consent ..................................................................................................................... 35
The role of the family and friends ............................................................................ 37
Preservation for transplantation ................................................................................ 38
Interventions prior to death ....................................................................................... 39
Coroners ...................................................................................................................... 40
Activities involving material from living adults who lack the capacity to consent .......... 41
Offences ..................................................................................................................... 42
Glossary ..................................................................................................................... 43
Annex A – Living Organ Donation guidance ............................................................. 44
Annex B – Flowcharts ............................................................................................... 55
Purpose of this Code of Practice

1. This Code of Practice provides practical advice and guidance on the Human Transplantation (Wales) Act 2013.

2. This Code of Practice is primarily intended for use by Specialist Nurses for Organ Donation (SNODs), other clinicians and professionals working in the transplantation sector in Wales. It may also be of interest to clinicians in other areas and specialities, as well as the public.

3. It is planned that the provisions of the legislation will come into force in summer 2015.
Authority under which this Code of Practice is produced

4. This Code of Practice is produced under section 26 of the Human Tissue Act 2004, as amended by section 14 of the Human Transplantation (Wales) Act.
The role of the Human Tissue Authority

5. The Human Tissue Authority (HTA) is the statutory regulator that supports public confidence by licensing organisations that store, use and remove human tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We also give approval for organ and bone marrow donations from living people.

6. In Wales, the HTA will continue to license establishments under the following legislation:
   - Human Tissue Act 2004
   - Human Tissue (Quality and Safety for Human Application) Regulations 2007
   - The Quality and Safety of Organs Intended for Transplantation Regulations 2012

7. As a regulatory body, the HTA does not have a role in making government policy. The HTA is required to provide advice and guidance to the legislatures in England, Wales and Northern Ireland on issues within its remit, including transplantation.
Overview

8. In England and Northern Ireland the Human Tissue Act 2004 governs consent to organ donation. In both nations it is unlawful to deem consent for organ donation. The same is true in Scotland, where the governing legislation on authorisation is the Human Tissue (Scotland) Act 2006.

9. The Human Transplantation (Wales) Act allows for consent to deceased organ donation to be deemed to have been given when a person dies in Wales, unless the person is either:
   a. A child under the age of 18
   b. An adult who has lived in Wales for less than twelve months
   c. An adult who has lived in Wales for more than twelve months but is not ordinarily resident there
   d. An adult who lacked the capacity to understand the notion of deemed consent for a significant period before their death.

10. When one of the categories a to d above applies, a person’s consent cannot be deemed, and express consent should be established or sought.

11. The Human Transplantation (Wales) Act is permissive in the sense that it allows consent to organ donation to be deemed in certain circumstances. However, it does not mandate that organ donation goes ahead in all such cases.

12. If a person made a decision in regard to organ donation when they were alive, their consent cannot be deemed. A decision made in life to be an organ donor should be acted on, where possible.

13. If a person appointed a representative/s to make a decision, their consent cannot be deemed. The decision of the appointed representative/s should be acted upon. If the appointed representative is unable to act, then the express consent of a qualifying relation may be sought.

14. In cases where there must be express consent this can mean the decision of the person in life, the decision of an appointed representative/s, or the decision of a person in a qualifying relationship.

15. The Human Transplantation (Wales) Act does not make any material amendments to the regulatory framework for living organ donation.
Information on the terminology used in this Code of Practice

16. Where the words “organ” or “organs” are used in this Code of Practice, they mean organs, part organs and tissue.

17. Where the phrase “organ donation” is used, this means organ and/or tissue donation after death, unless stated otherwise.

18. Throughout this Code of Practice the actions carried out by the Specialist Nurse for Organ Donation (SNOD) are sometimes described as taking place when the person is still alive. In some cases these actions will be undertaken by the SNOD after the decision has been made by the team treating the person that further treatment is futile, but before the person dies. In some cases they will be undertaken after the person has died. The same steps should be taken in both instances, unless stated otherwise.

19. Express consent means:
   a. the decision of a person when alive to either consent or not to consent to certain transplantation activities; or
   b. the decision of appointed representative/s on behalf of that person; or
   c. the decision of someone in a qualifying relationship with that person.

20. Deemed consent means that when a person did not make an active decision on organ donation during their life, or when they made an active decision but neither registered this or shared it with their family of friends, their consent to organ donation will be deemed to have been given, unless a person with a close relationship objects based on what they know of the wishes of the person.

21. When “family/friends” is used, this means the people providing information during the discussions about organ donation with the SNOD who identify themselves as having a relationship with the person, whether or not that relationship features on the list at section 17(2) of the Human Transplantation (Wales) Act.

22. When the phrase “fact and degree” is used, it means that the information presented and the information gained through questioning will need to be weighed up based on the quality of the facts it contains and the quantity of information.

Other documents which provide advice and guidance in this area

24. The HTA, as the statutory regulator, is required to provide advice and guidance on the Human Transplantation (Wales) Act.

25. There is a range of guidance and documentation on organ donation, transplantation and related matters which may be helpful to those using this Code of Practice.

26. These include (at the time of publication):

   a. HTA Codes of Practice
   b. HTA framework document on the quality and safety of organs intended for transplantation
   c. HTA guidance on living organ donation
   d. HTA guidance on tissue and cells for patient treatment
   e. Organ Donation (CG135) – NICE Guidelines
   f. UK Donation Ethics Committee on Donation after Brainstem Death (not yet published)
   g. UK Donation Ethics Committee on Donation after Circulatory Death
   h. Department of Health guidance on legal issues relevant to Donation after Circulatory Death
   i. Academy of Medical Royal Colleges Code of Practice on the diagnosis of death
   j. Mental Capacity Act 2005 Code of Practice
   k. Coroners and organ donation guidance
Who can seek consent

27. There is no requirement under the Human Transplantation (Wales) Act that the person seeking consent for deceased organ donation is of a specified grade or fulfils a certain role in the given institution.

28. Throughout this Code of Practice when reference is made to a person seeking consent, they are referred to as a SNOD. This reflects the National Institute for Health and Clinical Excellence (NICE) guidelines on consent for organ donation and NHS Blood and Transplant’s (NHSBT) policies and processes.

29. This does not mean that only a SNOD can seek consent. However, if the person seeking consent is not a SNOD, it is recommended that they meet the criteria in recommendations 1.1.30 and 1.1.31 of the NICE guidelines on consent.
Qualifying relationships

30. The Human Transplantation (Wales) Act includes at section 17(2) and the Human Tissue Act at section 27(4), a list of qualifying relationships:

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

31. A person is another person’s partner if the two of them lived as partners in an enduring family relationship. They can have different sexes or be of the same sex.

32. A friend of longstanding is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD may ask questions and/or request evidence as necessary to establish what degree of friendship existed.

33. For the purpose of providing information that the person did not want to be a donor in circumstances where consent can be deemed, this evidence can be provided by either a relative or a friend of long standing.

34. When the person is an excepted adult (please see paragraph 69, b-d), and they did not make a decision in life or appoint a representative/s, then the list will be ranked in accordance with section 27(4) of the Human Tissue Act.

35. When a person is a child, and they didn’t make a decision in life and there was no-one with parental responsibility for them immediately before they died, then the list will be ranked in accordance with section 27(4) of the Human Tissue Act.

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

37. In a situation in which the list is ranked:

   a. when an appointed representative is unwilling or unable to act; or
b. when the person is an excepted adult and did not appoint a representative/s; or

c. when the person is a child who had not made a decision and there was no-one with parental responsibility for them before they died,

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

38. In a situation in which the list is ranked (see paragraph 37, a-c) and agreement cannot be reached between people of a different rank, it is lawful to proceed with the consent of the person with the highest ranking relationship. This does not mean that the consent of that person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.
Legislative frameworks

Deceased organ donation

39. The Human Transplantation (Wales) Act makes provision for the consent (whether deemed or otherwise) that is required for all aspects of deceased organ donation carried out for the purpose of transplantation, for people who both live and die in Wales.

40. Deemed consent means that when a person (who is neither an excepted adult nor a child) did not make a decision in regard to organ donation after their death, or they made a decision but did not record or share this, their consent will be deemed to have been given.

41. There are circumstances when consent to organ donation in Wales cannot be deemed (see 69 to 70), and in these cases express consent is required before organ donation can proceed.

42. The meaning of express consent will depend on the circumstances of the donation. For example, if a person had made a decision about consent before their death then this will be express consent. Alternatively, if the person had not made such a decision then express consent means the consent of any appointed representative/s or the consent of persons in qualifying relationships. The remainder of this Code of Practice explains what kind of express consent is required in each case.

Living organ donation

43. The Human Transplantation (Wales) Act does not materially change the current UK law on living organ donation. The current law is set out in the Human Tissue Act and the Human Tissue (Scotland) Act and regulations made under them. More information on consent to living organ donation can be found at Annex A at the end of this document.

44. However, the Human Transplantation (Wales) Act does cover other aspects of the living donation process, in particular the storage and use of organs for the purpose of transplantation. In these circumstances, the living donor’s express consent will be needed.

Research

45. Deemed consent does not apply to the donation of organs for research purposes.
46. It is common practice for a discussion on the removal and use of organs for research to take place between a SNOD and the family/friends of the deceased when information is being gathered to facilitate organ donation. As consent/authorisation to research continues to be governed by the Human Tissue Act in England, Wales and Northern Ireland, and the Human Tissue (Scotland) Act in Scotland, express consent from the highest ranking person on the qualifying list (found in section 27(4) of the Human Tissue Act) will be required for the removal of material for the purpose of research to be lawful (unless the person made a decision in life in regard to research, or nominated a representative to do so).

**Licensing arrangements**

47. Since August 2012 establishments which carry out organ donation or transplantation activities must be licensed under the Quality and Safety of Organs Intended for Transplantation Regulations.

48. The HTA is the Competent Authority for the whole of the UK, and carries out audits to ensure establishments are compliant with the requirements of the Regulations. Part of the audit process concerns the processes in place for seeking and recording consent.

49. In order to meet the HTA’s standards on consent, an establishment located in any part of the UK must be able to demonstrate that it has in place policies and practices which ensure that legal requirements relating to consent/authorisation are met, whether this is under the Human Transplantation (Wales) Act, the Human Tissue Act, or the Human Tissue (Scotland) Act.
Types of organ donation after death

50. There are two types of organ donation after death which are undertaken in the UK. In Wales consent to either Donation after Brainstem Death (DBD) or Donation after Circulatory Death (DCD) can be deemed under the Human Transplantation (Wales) Act.

Donation after Brainstem Death

51. Donation after Brainstem Death (DBD) may take place following tests that have established that the person no longer has any brainstem function. Patients declared brainstem dead may have suffered head trauma, for example in a car accident, or a stroke. The patient’s organ support, including mechanical ventilation, is maintained while consent is established or sought.

Donation after Circulatory Death

52. Donation after Circulatory Death (DCD) may take place following the diagnosis of death by cardio-respiratory criteria.

53. DCD may be either controlled or uncontrolled. Controlled DCD describes organ retrieval which follows the planned limitation or withdrawal of life-sustaining treatment at the end of a critical illness from which the person cannot recover. Uncontrolled DCD occurs following a sudden, irreversible cardiac arrest.
Transplantation activities

54. For the purposes of the Human Transplantation (Wales) Act, transplantation activities are as follows:

   a. Storing the body of a deceased person for the purpose of transplantation.

   b. Removing from the body of a deceased person, for the purpose of transplantation, any relevant material of which the body consists or which it contains.

   c. Storing for use for transplantation any relevant material which has come from a human body.

   d. Using for transplantation any relevant material (see paragraph 59) which comes from the human body.

55. Deemed consent can apply to any of the transplantation activities at a to d above, if the conditions in the rest of this Code of Practice are met.

56. The storage and use of relevant material for the purpose of transplantation is lawful without the need for consent in Wales when the material has been lawfully imported into Wales, and lawful removal of the material from a person’s body took place outside Wales.

57. This means that when an organ is imported into Wales from another country it is not necessary for consent to be sought in Wales in order for the organ to be stored or used. However, as the statutory regulator for England, Scotland, Wales and Northern Ireland the HTA advises that:

   a. When the organ is imported from England or Northern Ireland consent under the Human Tissue Act must be in place.

   b. When the organ is imported from Scotland authorisation under the Human Tissue (Scotland) Act must be in place.

58. When the organ is imported from another country the HTA recommends it is best practice to ensure that consent for donation for transplantation was in place in-line with the legal framework in operation in that country.
Relevant material

59. Relevant material for the purpose of the Human Transplantation (Wales) Act is defined as material, other than human eggs and sperm, which consists of or includes human cells.

60. Relevant material from a human body, does not, for the purposes of the Human Transplantation (Wales) Act include:

   a. Embryos outside the human body, or
   b. Hair and nail from the body of a living person.

61. More information on relevant material can be found on the HTA website.
Novel transplants

62. The Human Transplantation (Wales) Act makes provision at section 4(5) for Welsh Ministers to make Regulations setting out which organs will not be included in the deemed consent system. A list of such organs and tissues will be published on the NHSBT website and the HTA website, and this will be updated when changes are made to the list.

63. If an organ is on this list, then express consent must be in place for removal, storage or use for the purpose of transplantation to be lawful.
Organs which are not listed on the Organ Donor Register

64. When an individual had registered their wish to become an organ donor on the Organ Donor Register (ODR), and had selected the option to donate any or all of their organs, in Wales this is express consent to the donation of organs which are on the ODR list on NHSBT’s website at the time of donation. This is not, however, express consent for donation of organs which do not appear on the ODR list of organs.

65. If specific organs do not appear on the ODR list, the SNOD should establish whether the person had recorded their decision regarding these organs somewhere other than the ODR, and act on this if they had.

66. If no such decision can be found in a reasonable timeframe, then the SNOD should check on the ODR to establish whether the person had appointed a representative (see paragraphs 134 to 145) to make a decision on their behalf.

67. If neither a decision nor an appointed representative is in place, then consent can be sought from a qualifying relation, if the organ does not appear on the list referenced in paragraph 62.
Deemed consent and express consent

69. In Wales, it is lawful to deem the consent of a person, unless one of the categories at points a to d applies.

Children

a. They are a person under 18 years old

Excepted Adults

b. They are an adult who had lived in Wales for less than twelve months at the time of their death

c. They are an adult who had lived in Wales for twelve months or more, but was not ordinarily resident in Wales

d. They are an adult who lacked mental capacity to understand the notion of deemed consent for a significant period before their death.

70. When a person is not within one of the categories above, it is lawful for their consent to organ donation to be deemed, unless:

a. They made a decision in life in regard to organ donation

b. The appointed a representative/s to make decision on organ donation on their behalf

c. A relative or friend of long standing objects on the basis of what they know about the deceased’s views

d. The transplantation activity involves material of a type specified by Welsh Ministers in Regulations.

71. If an excepted adult had made a decision before death to be an organ donor, this should be acted upon, when possible.

72. If an excepted adult had not made a decision, the SNOD should seek to establish whether they appointed a representative/s. Checking the ODR and asking any family/friends present or contactable if they are aware of any appointed representatives are considered to be reasonable and sufficient steps to take.

73. If, following these checks the SNOD does not have any reason to believe that there is an appointed representative/s, they should record this in the person’s medical record or other appropriate document. If there is not an appointed representative/s, for people who are excepted adults, the SNOD should seek consent from a person in a qualifying relationship in accordance with the ranking set out in section 27(4) of the Human Tissue Act.
74. To appoint a representative under section 7 of the Human Transplantation (Wales) Act there are specific requirements (see paragraphs 140 to 145), and this role is not the same as someone who has power of attorney or has been nominated to act under other pieces of legislation.
Establishing whether deemed consent applies

Children

75. In the majority of cases the SNOD will be able to establish easily the age of the person.

76. If the person is under the age of 18 it is unlawful for their consent to be deemed.

77. Deemed consent may apply to a person from 00.00 on the day of their eighteenth birthday.

78. It is recommended that medical records are checked to confirm the date of birth. If there is uncertainty as to whether the date of birth is accurate, for example the deceased person may have been born outside the UK and not issued with a birth certificate, then a conversation should take place with family/friends to establish the person’s age. This conversation does not have to be face-to-face, and could be conducted by phone, email, video conferencing, video calling or any other method as practical. A note of the conversation should be made in the person's medical record or other appropriate document.

79. If it is not possible to establish that the person is over the age of 18, then the express consent process should be followed.

80. Organ donation remains a possibility for people under the age of 18 who die in Wales. If the young person had competence and made a decision to donate or not to donate during their life then this constitutes express consent (or express non-consent).

81. One way a young person may have done this is by registering their decision on the ODR. When making a decision on whether the young person had the competence to consent, the SNOD should rely on the most recently published Department of Health guidance.

82. The table below is taken from section 6 of the Human Transplantation (Wales) Act and provides a useful summary of the meaning of express consent in every case that may involve children:
### Case | Meaning of express consent
--- | ---
1. The child is alive and case 2 does not apply. | The child’s consent.
2. The child is alive, no decision of the child to consent, or not to consent, to the activity is in force, and either the child is not competent to deal with the issue of consent or is competent to deal with the issue but fails to do so. | Consent of the person who has parental responsibility for the child.
3. The child has died and a decision of the child to consent, or not to consent, to the activity was in force immediately before death. | The child’s consent.
4. The child has died and no decision of the child to consent, or not to consent, to the activity was in force immediately before death. | Consent of a person who had parental responsibility for the child immediately before they died, or where no such person exists, the consent of a person in a qualifying relationship to the child at that time.

83. If a person under the age of 18 dies in Wales and had not made a decision during their life, consent may be sought from a person who had parental responsibility for that child immediately before they died.

84. If there is no-one alive who had parental responsibility for the child immediately before they died, consent can be sought from a person who had a qualifying relationship with the child at the time they died in accordance with the ranking set out at section 27(4) of the Human Tissue Act.

85. Where the express consent of a person with parental responsibility is required and they state they will not consent to organ donation, it is not possible to seek consent from someone in a qualifying relationship.

86. If there is more than one person with parental responsibility, and they cannot come to agreement on whether donation should go ahead, it is lawful for donation to proceed with the consent of just one person with parental responsibility. However, it is recommended that the SNOD seeks to support those with parental responsibility to reach a consensus.
87. Donation does not have to go ahead, even if there is the consent of a person with parental responsibility. The SNOD should consider the needs of all the people with parental responsibility.

88. Children cannot appoint a representative under section 7 of the Human Transplantation (Wales) Act.
Exempted Adults

What is meant by “in Wales”?

89. For the purposes of the Human Transplantation (Wales) Act “in Wales” means within a Welsh local authority. Information on the local authorities can be found on the Welsh Local Government Association website.

90. If an individual is unsure whether they live in a Welsh local authority area this can be established by checking the Gazetteer.

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

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

93. In the event that the Gazetteer is unavailable, then the SNOD should make other appropriate checks to establish whether the person lived in Wales.

Residency

94. In the majority of cases a SNOD will be able to establish where the deceased person lived, and whether they were ordinarily resident at an address in Wales.

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

96. For example, a person dies in a Welsh hospital on 15 February. It is established by speaking to their family/friends that they moved to Wales on 16 February of the same year. Deemed consent does not apply to them, as they had not lived in Wales for twelve calendar months when they died.

97. Had the person’s friends/family confirmed that they had moved to Wales on 15 February, and that the person was ordinarily resident in Wales, deemed consent would apply to them, as they had lived in Wales for twelve months when they died.
98. The twelve month period test does not involve counting the number of days a person had lived in Wales. Rather, it is necessary to establish that a person had lived in Wales for twelve calendar months.

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

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

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

**Ordinarily Resident**

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

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

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

   c. The person’s residency in Wales supported the regular order of their life for the time being.
      The person may have had temporary absences from Wales and still be considered ordinarily resident. The SNOD will need to gather evidence in such circumstance and make a decision on whether the person's residence supported the order of their life.
103. These qualities must be assessed on a case by case basis, and whether the qualities have been satisfied will primarily be a question of fact and degree. In many cases the SNOD will be able to establish easily whether the person’s residence was characterised by the qualities above. When it is not initially clear that this is the case, it is recommended that there is a discussion with family/friends to gain more information about how the person would have characterised their residency in Wales.

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

105. For example, a person may work in Cardiff and live there four nights a week, and spend the other three nights at their family home in Bristol. The SNOD should ask questions of the family and friends to establish how the person would have identified their residency. The SNOD may wish to ask where the person would have referred to as home. It will then be for the SNOD to weigh up the evidence to establish whether or not the person was ordinarily resident in Wales.

Students

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

Prisoners

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

Other groups

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

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

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

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

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

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

   b. If there is no indication in the medical records of a condition or illness which may have impacted the person’s capacity to understand deemed consent, the issue of mental capacity should be raised by the SNOD when speaking to the friends/family to inform them that consent will be deemed, in order to check that the person did have capacity. It is envisaged that this would take the form of a simple question, for example, “Do you think that your relative/friend would have understood that consent to organ donation could be deemed?”

   c. If there is an indication in the medical records of a condition or illness that may have impacted on the person’s capacity to understand deemed consent, the SNOD should undertake further investigations which address the specific circumstances of the person’s condition or illness. For example, if the person had been in hospital for some time it may be appropriate to speak to member of the team caring for them to establish their level of understanding of medical and consent issues generally.

   d. Where there is evidence of an illness that may have impacted the person’s capacity to understand deemed consent, in most cases it will be the family/friends who are able to provide the SNOD with the most accurate information as to
whether they understood consent to organ donation could be deemed. The SNOD should ask the family/friends whether they believe the person had a level of capacity to understand deemed consent, or analogous notions. This may be a detailed discussion, and if at the end of this there is doubt as to whether the person could have understood the notion of deemed consent, then the express consent process should be followed.

**Significant period**

113. The Human Transplantation (Wales) Act requires a person to have lacked capacity to understand the notion of deemed consent for a significant period, to be a person excepted from deemed consent.

114. The significant period test is an objective one. The significant period must be long enough to make a reasonable person think that it would be inappropriate for deemed consent to apply. Note that the significant period only negates deemed consent; if the person had made a decision to consent, or not to consent, then that express consent remains in force regardless of a subsequent loss of capacity.

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

116. It is possible that a person may have once understood the notion of deemed consent, but then subsequently lost capacity a significant time ago. For example, if a person lost capacity due to an accident five years after the Human Transplantation (Wales) Act came into force, then they would have known and understood that consent could be deemed when they had capacity. However, in this scenario, the person’s previous knowledge of the law cannot be relied upon because they have lacked capacity subsequently for a significant period in which they might have chosen to opt out. Therefore it would be inappropriate to deem their consent and the express consent of an appointed representative/s or qualifying relation should be sought instead.

117. A person may have chosen when they had capacity in regard to organ donation, to appoint a representative/s to act on their behalf under section 7 of the Human Transplantation (Wales) Act. When this is the case, the consent of the appointed representative is required and the guidance at paragraphs 134 to 145 should be followed.

118. A person may have made an advance statement in regard to organ donation, and when a person lacked the capacity to understand the notion of deemed consent
for a significant period before their death the SNOD should ask family/friends whether such a statement exists. The existence of such a statement may help those in a qualifying relationship make a decision on behalf of the person when they did not make a decision in life, and there is not an appointed representative/s.

119. The table below is taken from section 5 of the Human Transplantation (Wales) Act and provides a useful summary of the meaning of express consent in every case that may involve excepted adults:

<table>
<thead>
<tr>
<th>Case</th>
<th>Meaning of express consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A decision of the excepted adult to consent, or not to consent, to the activity was in force immediately before death.</td>
<td>The excepted adult's consent.</td>
</tr>
<tr>
<td>2. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity.</td>
<td>Consent given by the person or persons appointed.</td>
</tr>
<tr>
<td>3. Case 1 does not apply and the excepted adult had appointed a person or persons to deal with the issue of consent in relation to the activity, but no one is able to give consent under the appointment.</td>
<td>Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.</td>
</tr>
<tr>
<td>4. None of cases 1, 2 or 3 applies in relation to the excepted adult.</td>
<td>Consent of a person who stood in a qualifying relationship to the excepted adult immediately before death.</td>
</tr>
</tbody>
</table>
Establishing whether a person made a decision during life

120. The Human Transplantation (Wales) Act provides that when a person had made a decision during life to either consent to, or not consent to, organ donation, that decision overrides the issue of deemed consent.

121. This means that if a person had made a decision to donate their organs then this decision establishes their consent. Their consent would not be deemed.

122. If a person had made a decision not to donate their organs then this decision establishes that they have not consented. It would be unlawful to deem the person’s consent.

123. When a person had neither made a decision about organ donation nor appointed a representative/s, then their consent may be deemed, unless they are a child or an excepted adult (see paragraphs 69 to 70).

124. The Human Transplantation (Wales) Act does not specify where a person should record their wishes in regard to organ donation. Therefore, the SNOD should take reasonable steps to ensure they have made appropriate checks to establish whether a person had made a decision during life.

125. If there is more than one recorded decision of the person, and these are contradictory, it is the decision recorded closest to the date of death that should be observed.

126. For example, a SNOD checks the ODR for the decision of a person whose life sustaining treatment was withdrawn on 2 November of a given year. There is a decision to consent to the donation of all organs which was recorded on the ODR on 25 January of that year. When the SNOD speaks to the family, the person’s wife produces a letter dated 3 March of the same year which explains that his decision was not to donate his organs. In this case it is the decision within the letter which should be observed as this was made closer to the date of death.

127. For the purpose of the Human Transplantation (Wales) Act, it is the date of the evidence presented, rather than the type of evidence (e.g. will or letter), which is material.

128. The HTA considers the steps at paragraphs 129 to 152 are the minimum to be taken by the SNOD when seeking to establish whether a person had made a decision on organ donation in life.
Organ Donor Register

129. The SNOD should check the ODR to establish whether the person had registered either a decision to, or not to, donate their organs. If there is a recorded decision the SNOD should share this information with the family.

130. If the recorded decision was to donate some or all organs, and the family state that the person had changed their minds and did not wish to donate their organs, they should be asked what evidence they have to show this is the case (see paragraphs 153 to 162).

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

132. If the SNOD accepts that the person has changed their mind, having previously recorded a decision not to consent on the ODR, then donation should not go ahead.

133. A recorded decision not to be an organ donor is a decision not to donate any organs, part organs or tissue. It is not just a decision not to donate the organs which feature on the ODR list.

Appointed representatives

134. If there is no decision recorded on the ODR, then the SNOD should make checks to establish whether the person appointed a representative/s to make a decision on their behalf in regard to organ donation.

135. The name and contact details of the appointed representative/s may have been recorded on the ODR, and this is the first check the SNOD should make. If there is a recorded appointed representative, the SNOD should contact them and ask them to make a decision on behalf of the person.

136. It is possible that the person made the appointment in regard to one or more of the transplantation activities (see paragraphs 54 to 58). The SNOD should ask the appointed representative if they are aware of any limitation on the transplantation activities they are able to consent to on behalf of the person.
137. If the appointed representative on the ODR cannot be contacted in time to make a decision, or is unwilling to make a decision, then a qualifying relation may be approached to make a decision about organ donation. The list of qualifying relations will be ranked in accordance with section 27(4) of the Human Tissue Act.

138. If there is no record of an appointed representative/s on the ODR, the SNOD should ask the family/friends of the person if they are aware of a person/s who were appointed representative/s to make decisions on organ donation.

139. If the SNOD is informed that there is an appointed representative/s, the checks at paragraphs 140 to 145 below should be undertaken to ensure they have authority under the Human Transplantation (Wales) Act.

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

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

   a. The document making the appointment was signed by the person in the presence of a witness who confirmed the signature; or
   b. It was signed by another person at the direction of and in the presence of the person, and in the presence of a witness who confirmed the signature; or
   c. It was contained in the will of the person, and that will was made lawfully.

142. If more than one person has been appointed, the default position is that the appointed representatives can make decisions jointly or separately. This means that the representatives do not have to agree, so one of them can give consent regardless of what the other representatives decide.

143. However, the appointment may provide that multiple representatives must act jointly. This means that all representatives must agree before consent can be established. In these circumstances, if one representative cannot be contacted then the representatives cannot give consent.

144. It may be the case that a person appointed representative/s but did not record them on the ODR or tell their family/friends about them. It is recognised that it is not practical for the SNOD to make numerous checks to establish whether a person appointed a representative/s. It is therefore considered adequate for a SNOD to check the ODR and to ask family/friends. It is important that a note is made of these checks and any discussions with family/friends.
145. If a person had nominated a representative/s under section 4 of the Human Tissue Act, they are considered an appointed person or persons for the purposes of the Human Transplantation (Wales) Act.

**Family and friends**

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

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

148. If the SNOD is informed that the person recorded their decision orally, the SNOD should speak with the person who was informed of the decision and make a note of the details of this conversation.

149. The SNOD will need to make a decision, based on the evidence presented to them, whether they are satisfied that this constitutes the person’s decision in life. It is considered that written, signed and dated evidence which was witnessed is most likely to satisfy the SNOD that this was the decision of the person in life.

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

151. If the SNOD is not satisfied that the evidence presented to them constitutes a decision of the person in life, then the person’s consent can be deemed (unless they are a child or an excepted adult).

152. If the SNOD is informed by family/friends that the person had not made a decision in life, then their consent to organ donation may be deemed (unless they are a child or an excepted adult).
Evidence which would satisfy a reasonable person that the person would not have given consent

153. If a person is not a child or an excepted adult, and they had not made a decision in life or appointed a representative/s, then their consent to organ donation may be deemed.

154. When this is the case the SNOD should inform those people present or contactable in a qualifying relationship with the person that consent may be deemed unless the family objects, based on what they know of the wishes of the person.

155. If the SNOD is informed by relatives or friends that the person would not have consented to organ donation, they should make reasonable enquiries as to why the relatives or friend thought that to be the case. In terms of who can object, the legislation provides for a relative or a friend of long standing to be able to do so.

156. When information is provided by a relative or friend of long standing that the person would not have consented, this must meet the test of satisfying a reasonable person.

157. In order to satisfy the reasonable person test, the SNOD should ask that they are presented with all the evidence to support the assertion that the person would not have consented.

158. When there is written evidence and this is signed by a witness, this would form the express consent of the deceased and so consent could not be deemed.

159. When there is written evidence and this has not been witnessed, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.

160. Where there is oral evidence, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.

161. The reasonable person test is an objective one, and involves the person making the assessment (in this case the SNOD), deciding how much weight the evidence has.

162. In order to assess the weight of the evidence presented, the following questions may be considered to aid the SNOD in reaching a decision:
a. Is the evidence presented as reflecting the views of the person, or the views of those in a qualifying relationship? The test requires that evidence must be presented of the person’s view. Therefore, more weight should be given to evidence which is presented as being a reflection of the person’s view.

b. Is the evidence in writing, signed and dated by the person and witnessed? If this is the case, then this is likely to form an express decision of the person.

c. Is the evidence oral? If so, is it corroborated by more than one person? It is more likely to pass the reasonable person test if more than one person is able to confirm that the person orally stated that they would not have consented to donation.

d. How recent is the evidence? The Human Transplantation (Wales) Act requires the most recent evidence to be relied on, therefore the SNOD should establish when the record was made or the conversation took place and note this in the person’s medical record or other appropriate document.

e. How well does the person providing the evidence know the person? It is not necessarily always the case that a person knows someone well simply because they are related. For example, a person may have a carer who is not related to them, but spends every day with them.
The role of the family and friends

163. The family and friends of a person have different roles under the Human Transplantation (Wales) Act in different circumstances.

164. Family and friends may be asked to provide medical and social background information on the person in order that a risk assessment can be carried out. This is not part of the consent process, but rather allows for clinical decisions to be made about organ donation in light of all the relevant information.

165. It is acknowledged that in some cases where there is express consent, or consent can be deemed, that the family/friends will feel very strongly that organ donation should not go ahead. In such circumstances it is recommended that the person's family/friends are given the information they require by the SNOD and sufficient time alone to reach a decision.

166. It should be noted that there is no requirement that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would be lawful for organ donation to take place.

167. On occasion, a person will die and there will not be any family/friends who can be identified. When this is the case, if the person had registered their decision to donate on the ODR, then the SNOD should refer to the guidance in the HTA’s framework on the Organ Donation Directive.

168. If there is no registered decision, and the person did not appoint a representative/s, and the person was not a child or an excepted adult then consent can be deemed; again the SNOD should refer to the guidance in the HTA's framework on the Organ Donation Directive.
Preservation for transplantation

169. The Human Transplantation (Wales) Act allows for steps to be taken to preserve part of the body of a deceased person when it is, or may be, suitable for transplantation, but consent or the absence of consent has not yet been established.

170. Please note that the provisions relate only to the preservation of a person after their death. Information on interventions prior to death is provided at paragraphs 175 to 179.

171. In order for preservation to be lawful, the body of the deceased person must be lying in a hospital, nursing home or other institution in Wales. For the purpose of this section “in Wales” has the same meaning as in paragraphs 89 to 93, and means within a Welsh local authority.

172. The steps which can be taken to preserve the body part/s for transplantation must be minimal and there is an obligation that the least invasive procedure is used.

173. The taking and storage of blood samples from a deceased person for the purpose of facilitating organ donation for transplantation is acceptable, as without such samples it is unlikely donation could go ahead if it is discovered that consent is in place. A licence under The Quality and Safety of Organs Intended for Transplantation Regulations 2012 must be in place in order for such blood samples to be taken and stored lawfully.

174. If it is established that express consent is not in place, and that consent cannot be deemed for the person, then the steps to preserve for the purpose of transplantation should cease or be withdrawn promptly, as applicable.
Interventions prior to death

175. The Human Transplantation (Wales) Act does not address the matter of steps which may be taken prior to the death of a person who may become a donor after circulatory death.

176. The steps which may be taken prior to the death of a person to facilitate DCD are detailed in the Department of Health document “Legal issues relevant to non-heartbeating organ donation” published in November 2009.

177. At the time of drafting this Code of Practice there are a number of reviews being undertaken to provide increased clarity and certainty to those working within organ donation and transplantation.

178. If the DH Guidance of November 2009 is revised, an update will be provided to this Code of Practice to reflect this.

179. It is important to note that interventions before death are governed by the Mental Capacity Act 2005, rather than the Human Transplantation (Wales) Act or Human Tissue Act.
Coroners

180. Where the person’s death is violent or unnatural, or is sudden and the cause is unknown, the matter of organ donation requires referral to the coroner and in such cases agreement (or a lack of objection) of the coroner should be sought before any transplantation activities can be undertaken, or steps can be taken to preserve the body part/s of the person.

181. It is recommended that SNODs seek to agree a working protocol with the appropriate coroner/s in the local area, in order that they are able to establish at an early stage whether the person’s body will be under the coroner’s authority, and whether the coroner will agree to steps being taken for preservation, and eventually for organ donation.
Activities involving material from living adults who lack the capacity to consent

182. Where an adult lacks the capacity to consent to the removal of an organ or part organ, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and following court approval the case is referred to, and assessed by, an HTA panel.

183. The Human Transplantation (Wales) Act does not specify the criteria for considering whether an adult has capacity to consent. The relevant legislation is the Mental Capacity Act.
Offences

184. A person commits an offence under the Human Transplantation (Wales) Act if they undertake a transplantation activity without consent.

185. This means that if a body is stored, or if relevant material is removed, stored or used for the purpose of transplantation without consent, then the person who carried out that activity will have committed an offence.

186. An offence is committed by a person if they represent to someone who either will or may undertake a transplantation activity that there is consent to that activity, or that the activity is not a transplant activity, when they know the representation to be false or do not believe it to be true.

187. For the purpose of offences under the legislation, consent means either express or deemed, depending on which type of consent should have been relied upon.

188. The person who committed the offence will be subject to a fine not exceeding the statutory maximum if summarily convicted.

189. If convicted on indictment, the person who committed the offence will be subject to:

   a. Imprisonment for a term not exceeding three years, or
   b. A fine, or
   c. Both.

190. If a person reasonably believed they were undertaking a transplant activity with consent, or they reasonably believed the activity they were undertaking was not a transplant activity, then no offence has been committed.

191. The test associated to reasonably believing is a subjective one. In order to prove that a person reasonably believed that consent was in place or the activity they had undertaken was not a transplantation activity, they would need to produce evidence which would satisfy a court.

192. There is, at the time of drafting this Code of Practice, no case law which provides information on the types of evidence which would satisfy a court that the person had a reasonable belief.
Glossary

**Authorisation**, in respect of a donor in Scotland, means: where the donor is an adult with capacity to give authorisation, Part 1 of the Human Tissue (Scotland) Act 2006; or the authorisation or lack of unwillingness of the donor referred to in, the Human Organ and Tissue Live Transplants Scotland Regulations 2006 (SI 2006 no. 390).

**Deemed consent** means that when a person did not make an active decision on organ donation during their life, or when they made an active decision but neither registered this or shared it with their family of friends, their consent to organ donation will be deemed to have been given, unless a person with a close relationship objects based on what they know of the wishes of the person.

**Donor** means a person who donates one or several organs, whether donation occurs during lifetime or after death.

**Donation** means donating organs for the purposes of transplantation.

**Express consent** means:

- the decision of a person when alive to either consent or not to consent to certain transplantation activities; or
- the decision of appointed representative/s on behalf of that person; or
- the decision of someone in a qualifying relationship with that person.

**Gazetteer** means TBC

**Novel transplant** means the transplantation of an organ or tissue which is on the list in the (TBC) Regulations.

**ODR** means the organ donor register.

**Organ** means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

**Tissue** means any and all constituent part/s of the human body formed by cells.

**Transplantation** means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.
Annex A – Living Organ Donation guidance

Living organ donation

The information in this Annex is taken directly from the HTA Code of Practice on the donation of solid organs for transplantation.

Types of living organ donation

1. The types of living organ donation currently offered in the UK are:

   a. Directed donation: A form of donation where a healthy person donates an organ (usually a kidney) or part organ (for example liver or lung lobe) to a specific recipient. The recipient could be known to the donor (in the case of genetically or emotionally related donation) or unknown to the donor (in the case of paired donation).

      i. genetically related donation: where the potential donor is a blood relative of the potential recipient

      ii. emotionally related donation: where the potential donor has a relationship with the potential recipient, for example, spouse, partner, or close friend

      iii. paired donation: where a relative, friend or partner is fit and able to donate an organ but is incompatible with the potential recipient, and they are matched with another donor and recipient in a similar situation, so that both people in need of a transplant receive a compatible organ

      iv. pooled donation: a form of paired donation whereby the pair are matched with other donors and recipients from a pool of pairs in similar situations, and more than two donors and two recipients are involved in the swap, so that more than two people in need of a transplant receive a compatible organ

      v. directed altruistic donation: where there is no genetic or pre-existing emotional relationship between the donor and recipient. These cases tend to be characterised by a third party - either a person or other mechanism such a social networking website - bringing the donor and recipient together for the purpose of transplantation

   b. Altruistic non-directed donation: A form of living donation whereby an organ (usually a kidney) or part organ (for example liver or lung lobe) is donated by
a healthy person who does not have a relationship with the recipient and who is not informed whom the recipient will be.

c. Non directed altruistic donor chains: where a non-directed altruistic donor donates their organ into the paired / pooled scheme. By matching two or more donors and recipients, a chain of operations can be carried out. The remaining organ at the end of the chain is then donated to the best matched recipient on the national waiting list.

2. Domino donation is a further form of living donation where an organ or part organ is removed for the primary purpose of a person's medical treatment. The organ/s removed may prove suitable for transplant into another person (e.g. a heart originally removed from the recipient of a heart / lung transplant). The HTA does not regulate domino donations. While consent for use of the organ for transplantation does fall under the consent requirements of the HT Act, the donation would not be subject to the same regulatory requirements as other types of living donation. This is because, although it is a living donation, the donation primarily arises from the removal of the organ as part of a patient's treatment. Consent to treatment and examination is covered by the common law, and the legal position is set out in Department of Health's guidance.

Requirements of the legislation

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

4. Consent for the removal of organs from living donors, whether for transplantation or otherwise, is outside the scope of the HT Act. It is instead covered by the common law and the Mental Capacity Act (MC Act) 2005 where appropriate. Trusts should have local policies in place for obtaining consent to treatment and the legal position is set out in the Department of Health’s guidance. Guidance for healthcare professionals in Wales is available in the Welsh Assembly Government’s Reference guide to consent for examination and treatment. The Department of Health, Social Services and Public Safety (DHSSPS) (Northern Ireland) has published its own Reference guide to consent for examination, treatment or care.

5. The requirements for living donor transplantation are set out in sections 33 and 34 of the HT Act and 9–14 of the Regulations.

6. It is an offence to remove or use any organ or part organ from the body of a living person for transplantation unless the requirements of the HT Act and the Regulations are met.
7. The Regulations require that, with the exception of domino donations, all living organ donations for transplantation must be approved by the HTA before the donation can take place.

8. Before the HTA can approve such cases, the Regulations require that the Authority must be satisfied that:
   
i. no reward has been, or is to be, given
   
ii. consent to removal for the purpose of transplantation has been given (or removal for that purpose is otherwise lawful)
   
iii. an Independent Assessor (IA) has conducted separate interviews with the donor (and if different from the donor, the person giving consent) and the recipient (or the person acting on behalf of the recipient) and submitted a report of their assessment to the HTA.

9. A person is qualified to conduct such an interview if:
   
i. they meet the HTA’s person specification for becoming an IA and have completed the approved HTA training, and enhanced training for the assessment of directed altruistic donation cases
   
ii. they do not have any connection to those being interviewed, or their families, of a kind which the HTA considers might raise doubts about impartiality
   
iii. in the case of an interview with the donor (or other person giving consent), the IA is not the same person who gave them information about the procedure and its risks.

10. The Regulations also specify the matters to be covered in the report submitted by the IA to the HTA, which are:
   
i. the information given to the potential donor (or other person giving consent) as to the nature of the medical procedure and the risk involved
   
ii. the full name of the person who gave that information to the potential donor (or other person giving consent), and their qualification to give it
   
iii. the capacity of the potential donor (or other person giving consent) to understand the nature of the medical procedure and the risk involved and that consent may be withdrawn at any time before the removal of the organ or part organ
   
iv. whether there is any evidence of duress or coercion affecting the decision to give consent
v. whether there is any evidence of an offer of a reward

vi. whether there were any difficulties in communicating with the person interviewed (e.g. language, hearing), and if so, an explanation of how these difficulties were overcome

11. There are two levels of decision-making for living organ donation: the first where the HTA transplant approvals team can make the final decision on a case; and the second where a case must be assessed by an HTA panel.

12. A decision on a transplant must be made by an HTA panel:
   i. if the donor is a child
   ii. if the donor is an adult who lacks capacity to consent to removal of an organ or part organ
   iii. in all cases of paired and pooled donation
   iv. in all cases of altruistic non-directed donation
   v. where the Authority has decided not to delegate decision making (currently adult-to-adult liver, directed altruistic, or economic dependence donation cases)

13. All other cases can be approved by the HTA transplant approvals team, although they can also refer complex or novel cases to a panel where required.

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

Payment, advertising and commercial dealings

15. The HT Act allows donors to receive reimbursement of expenses, such as travel costs and loss of earnings, which are reasonably attributable to and directly result from donation.

16. Details on the levels of reimbursement are available in the guidance on Reimbursement of living donor expenses by the NHS.

17. The HTA requires that checks are made to ensure that no other payment or reward is made and that the donor does not profit from the donation.
18. The HT Act also prohibits commercial dealings in human material, including organs or part organs, for the purposes of transplantation. A person is committing an offence if they:

i. give, offer or receive any type of reward for the supply or offer of supply of any organ or part organ

ii. look for a person willing to supply any organ or part organ for reward

iii. offer to supply any organ or part organ for reward

iv. initiate or negotiate any arrangement involving the giving of a reward for the supply of, or for an offer to supply, any organ or part organ

v. take part in the management or control of any type of group whose activities consist of or include the initiation or negotiation of such arrangements

vi. cause to be published or distributed, or knowingly publish or distribute, an advertisement inviting people to supply, or offering to supply, any organ or part organ for reward, or indicate that the advertiser is willing to initiate or negotiate any such arrangements. This covers all and any types of advertising

19. This offence carries the risk of a fine and up to three years imprisonment. No offence is committed, however, where payments relate to reimbursement of the donor’s expenses as discussed above, or reimbursement is for relevant expenses connected with transporting, removing, preparing, preserving, or storing human material for the purpose of transplantation.

**Children – special considerations**

20. Children can be considered as living organ donors only in extremely rare circumstances. In accordance with common law and the Children Act 1989, before the removal of a solid organ or part organ from a child for donation, court approval should be obtained. Further guidance on seeking court approval can be found in Appendix A.

21. Living donation by a child under the HT Act can only go ahead with the approval of an HTA panel. The HT Act defines a child as being under 18 years old. Such cases should only be referred to the HTA for decision after court approval to the removal has been obtained.

22. The position in Scotland regarding children is somewhat different and the Scottish Government has issued guidance on these cases.
Adults – special considerations

23. Where an adult lacks the capacity to consent to the removal of an organ or part organ, the case must be referred to a court for a declaration that the removal would be lawful. Donation may then only proceed if court approval has been obtained and following court approval the case is referred to, and approved by, an HTA panel.

24. The HT Act does not specify the criteria for considering whether an adult has capacity to consent.

25. In determining whether a person of 16 or over has capacity, the provisions of the MC Act should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website and in the MC Act code of practice. There is separate guidance for Wales and for Northern Ireland. The Adults with Incapacity (Scotland) Act 2000 governs adults who lack capacity in Scotland.

26. The position in Scotland regarding adults with incapacity and living organ donation is somewhat different and the Scottish Government has issued guidance on these cases.

Scottish legislation

27. The legal framework for living organ donation and transplantation is different in Scotland, and is set out in section 17 of the HT (Scotland) Act 2006. These provisions are supplemented by the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 (the Scottish Live Transplants Regulations).

28. Under Scottish legislation, adults without capacity to make their own decisions and children (defined as persons who have not yet reached the age of 16) are only able to donate solid organs or part of an organ which has to be removed as part of a domino organ transplant operation. Unlike other forms of living organ donation this form of donation is not regulated by the HTA. Guidance within this code is not therefore applicable to adults with incapacity or children in Scotland.

29. Scottish law covering living organ donation by adults with capacity is broadly similar to that which applies in the rest of the UK, although in Scotland a person becomes an adult when they reach the age of 16.

30. Scottish Ministers have asked the HTA to regulate donation approvals on their behalf.

HTA process

Roles of the HTA
31. As required by the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006, the HTA must assess all cases of living organ donation (except domino donations) for transplantation. The HTA undertakes this role through an independent assessment process.

32. Before a transplant involving a living donor takes place, a donor and recipient must receive a full medical assessment to determine whether they are suitable to undergo the procedure. The decision about whether a person is medically fit and suitable as a living organ donor is a matter for the practitioners concerned. Additionally, the Q & S Organs Regulations set out the mandatory requirements for donor and organ characterisation, and further information on this can be found in the HTA’s publication ‘The Quality and Safety of Organs Intended for Transplantation – a documentary framework’. If the donor is deemed suitable, the clinician responsible for the donor must then make a written referral to an HTA IA.

**Independent Assessors (IAs)**

33. In order to become an IA, a person must have completed the training and have been accredited by the HTA to undertake the role. Further guidance on IA accreditation can be found in the Guidance for transplant teams and Independent Assessors.

34. IAs are professionals who are usually, but not exclusively, based in hospitals with transplant units or referring nephrology units. IAs act as a representative of both the HTA and the donor in order to help the HTA ensure the requirements of the HT Act and Regulations have been met.

35. The IA’s responsibility is to interview the donor and recipient to assess whether the requirements of the HT Act and Regulations have been met. Separate interviews must be carried out with the donor and recipient, and IAs also interview the donor and recipient together.

36. The exceptions to this are:

   i. when the recipient is a child, the donor will be interviewed separately and the IA would attempt an interview with the child recipient. If an interview could not be undertaken with the recipient the IA would note this in their report to the HTA.

   ii. in non-directed altruistic donation, the IA would only see the donor.

   iii. an application is made to the HTA to suspend the requirement that donor and recipient be interviewed together, and this is approved.

37. Following the interview the IA must prepare a report for the HTA which states whether they are satisfied that the relevant requirements of the HT Act and Regulations have been met.
**HTA approval process**

38. Following submission of the IA’s report, the HTA will make a final decision on approval of the donation.

39. All straightforward directed donations where the donor and recipient are genetically or emotionally related can be assessed by the HTA transplant approvals team. However, the transplants approval team is able to refer complex cases (including those relating to newer types of organ transplant) to a panel for decision.

40. Decisions on all other donations must be made by a panel of Authority members. These include altruistic non-directed donation, paired or pooled donation, donations by children, and donations from adults who lack capacity to consent. In the rare case of donation by a child or an adult who lacks capacity, an HTA panel will consider the case only after a court declaration has been made on whether the proposed intervention is lawful. See Appendix A for requirements for court approval.

**HTA panels**

41. HTA panels consist of three Authority members. A panel may ask the advice of experts; however, these advisors are not involved in the final decision-making on a donation. Panels are supported by the HTA transplant approvals team.

42. Detailed information on the referral, assessment and approval process for each type of donation is available in the Guidance for transplant teams and Independent Assessors.

**Consent**

43. The HT Act requires consent be obtained to use organs or part organs from a living person for transplantation.

44. The giving of consent is a positive act. For consent to be valid, it must be given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

45. Obtaining valid consent presupposes that there is a process in which individuals, including their partners, relatives or close friends where appropriate, may discuss the issue fully, ask questions and make an informed choice. Sufficient time should be allowed for questions and discussion. Surgeons should always check before surgery that the person still consents to the procedure, and be clear that consent has not been withdrawn before they proceed.

46. While the HT Act does not specify the format in which consent should be given or recorded, it is good practice to obtain written consent for significant procedures such
as organ donation. When consent is obtained but is not in writing, this should be clearly documented in the patient’s records. The record should detail when consent was obtained and the purposes for which the consent was given. It is also good practice to document details of discussions held regarding the risks of the procedure.

47. Further guidance on consent and the HT Act is available in the code of practice on Consent.

Consent – adults

48. For consent to be valid it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question.

49. The HT Act does not specify the criteria for considering whether an adult has capacity to consent.

50. Under the MC Act, a person aged 16 and over is unable to make a particular decision if they cannot do one or more of the following things:

   i. understand the information given to them that is relevant to the decision
   ii. retain that information long enough to be able to make the decision
   iii. use or weigh up the information as part of the decision-making process
   iv. communicate their decision by any means

   Full guidance on how the MC Act defines capacity and how it should be assessed is given in chapter 4 of the MC Act code of practice.

51. The provisions of the MC Act should be considered together with general principles governing capacity to consent to medical procedures. Guidance is available from the Office of Public Guardian website and in the MC Act code of practice. There is separate guidance for Wales and for Northern Ireland. The Adults with Incapacity (Scotland) Act 2000 governs adults who lack capacity in Scotland.

52. The MC Act governs decision-making on behalf of adults (aged 16 and over) who lack capacity to make a particular decision because the way their mind or brain works is affected. For the purposes of the MC Act, unlike the HT Act, an adult is a person aged 16 or over. The MC Act only applies to persons aged 16 or over.

53. There are detailed provisions contained in the MC Act concerning decisions made on behalf of adults lacking capacity. All decisions must be made in the person’s best interests, as laid out in chapter 5 of the MC Act code of practice. Also, certain categories of people have a legal duty to have regard to the MC Act code of practice,
when working with or caring for individuals who lack or may lack capacity to make decisions for themselves, as laid out in chapter 6.

54. The MC Act defines persons who lack capacity, see chapter 4 of the MC Act code of practice, and contains a set of key principles and a checklist to be used in ascertaining best interests, see chapter 5 of the MC Act code of practice. The first core principle of the MC Act is that an adult must be assumed to have capacity to make a decision for themselves, unless it is established that they lack capacity to make the particular decision at the time the decision needs to be made.

55. It should therefore always be assumed that an adult has the capacity to make a decision unless there is reason to believe otherwise.

Consent – children

56. Under the HT Act, a child is defined as being under 18 years old. Under the HT (Scotland) Act, a child is defined as being under 16 years old.

57. The removal of an organ or part organ from a child is governed by the common law and the Children’s Act 1989. Before any such procedure the approval of a court should be sought. Appendix A to this code provides further guidance on requirements for court approval.

58. The HT Act requires consent be given for the storage and use of organs for transplantation. Where a child is deemed competent to consent to that decision, the necessary consent will be their own. A person who has parental responsibility for the child can consent to the storage and use of organs for transplantation on the child’s behalf if there is no decision by the child either to, or not to, consent, and:

   i. the child is not competent to deal with the issue of consent to donation

   ii. even though the child is competent to do so, they have not made a decision about consent to donation

59. A person who has parental responsibility will usually, but not always, be the child’s parent. The category of persons with parental responsibility is as set out in the Children Act 1989.

Informing the donor

60. Potential donors must be provided with sufficient information for them to reach an informed decision about whether they wish to give consent. This information should be provided by the transplant team before the donor is interviewed by an IA.
61. All potential donors should be provided with a copy of the HTA leaflet Information about living donor transplants.

62. The following information should be explained in full to the donor:

i. the surgical procedures and medical treatments involved for the donor and the risks involved in both the short-and long-term (this should be explained by a medical practitioner with appropriate qualifications to give this information)

ii. the chances of the transplant being successful and any possible side-effects or complications for both donor and recipient

iii. the right to withdraw consent at any time, and the implications of doing so

iv. their right to be free of any kind of coercion or threat against them or anyone else (for example, family or friends) and that consent seen to be given under any such pressure will not be validated by the IA

v. the fact that it is an offence to seek or receive payment or any other reward for providing organs or part organs for transplantation, and that this offence is subject to significant penalties

vi. donors are able to seek reimbursement of expenses, such as travel costs and loss of earnings that are reasonably attributable to and directly result from donation.

63. Information should be provided to the donor about the risks and potential complications or side effects for the recipient, as information on factors which could impact the life of the graft, or the recipient themselves, may be material to the donor's decision-making process, and ensures fully informed consent can be given. Relevant information will vary on a case-by-case basis, and transplant teams should share information with donors following prior agreement with the potential recipient.

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

64. In respect of potential altruistic non-directed and paired or pooled donors the following information should also be provided:

i. anonymity of the donor and recipient is required before the operations, and that confidentiality must be respected

ii. how the altruistic donor, paired or pooled process works and how suitable recipient/s, or in the case of paired or pooled donation suitable matches, are identified.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

Annex B – Flowcharts
Flowchart A – Overview of deemed and express consent

- **Does the organ appear on the list in the xx Regulations?**
  - Yes: Consent must be express
  - No: **Is the person a child under 18?**
    - Yes: Consent must be express
    - No: **In the person an excepted adult?**
      - Yes: Consent must be express
      - No: **Is express consent in place?**
        - Yes: Consent must be express
        - No: Consent may be deemed. See flowchart D

Consent must be express.
Flowchart B – Can deemed consent apply to the person?

- Is the person aged 18 or over?
  - No
    - Follow express consent process. See Flowchart E
  - Yes
    - Did the person lack capacity for a significant period before their death?
      - Yes
        - Consent may be deemed, if no express consent in place. See Flowchart C
      - No
        - Was the person ordinarily resident in Wales?
          - Yes
            - Consent may be deemed, if no express consent in place. See Flowchart C
          - No
            - Follow express consent process. See Flowchart E

- Had the person lived in Wales for more than six months?
  - Yes
    - Consent may be deemed, if no express consent in place. See Flowchart C
  - No
    - Follow express consent process. See Flowchart E
Flowchart C – Is there express consent in place?

Is there an appointed representative?

- **Yes**
  - Can they be contacted? Are they willing and able to make a decision?
    - **Yes**
      - The decision of the appointed representative is express consent
    - **No**
      - Had the person recorded a decision on the ODR?
        - **Yes**
          - The decision on the ODR is express consent
        - **No**
          - Had the person recorded a decision elsewhere?
            - **Yes**
              - The recorded decision is express consent
            - **No**
              - Consent may be deemed, unless evidence is presented that the person would not have wished it to be. See Flowchart D.

- **No**
  - Had the person recorded a decision on the ODR?
    - **Yes**
      - The decision of the appointed representative is express consent
    - **No**
      - Consent may be deemed, unless evidence is presented that the person would not have wished it to be. See Flowchart D.
Flowchart D – Is there evidence to overturn deemed consent?

1. Is evidence presented that the person would not have wanted their consent to be deemed?
   - No: Consent may be deemed
   - Yes: Is the evidence presented by a relative or close friend of the person?
     - No: Consent may be deemed
     - Yes: Would a reasonable person consider the evidence credible?
       - No: Consent may be deemed
       - Yes: Is the evidence the most recent available?
         - Yes: Consent cannot be deemed
         - No: Access the most recent evidence
Flowchart E – Express consent process

Had the person recorded a decision on the ODR?

Yes

The decision on the ODR is express consent

No

Had the person recorded a decision elsewhere?

Yes

The recorded decision is express consent

No

Is there an appointed representative?

Yes

Can they be contacted? Are they willing and able to make a decision?

Yes

The decision of the appointed representative is express consent

No

The decision of a person in a qualifying relationship is express consent. The hierarchy is ranked for this decision

No

The decision on the ODR is express consent

Yes

The decision of the person in a qualifying relationship is express consent. The hierarchy is ranked for this decision

No

If there is not a person in a qualifying relationship, donation should not go ahead
Financial Report - March and April 2013

Purpose

1. This paper provides an update of the HTA's financial position as at 31 March 2013, from the draft year end accounts, and highlights of the position at the end of April.

2. The report provides commentary on the following areas:
   - financial position at year end
   - budget for 2013/14
   - position at 30 April 2013
   - financial risks.

Action

3. The Authority is asked to note the financial position at year end and at 30 April 2013.

Decision making process to date

4. This report has also been made to the Senior Management Team and is to note.

Financial position at year end

5. The annual accounts and reports have been drafted and are being audited from 13-24 May. The key points are set out below. An update following the audit will be provided at the Authority meeting.

6. The Audit Committee will review the accounts and reports at its meeting on 4 June, together with the report from the NAO (the ISA 260 Report). The
Committee inform the signing of the annual report and accounts by the Chief Executive, before certification by the Comptroller and Auditor General. The report and accounts are then laid before Parliament and published. We expect publication at the end of June.

7. The key points from the draft annual accounts are as follows.

8. Expenditure was £4,239k for the year. This was £442k (9%) less than budget, for the reasons explained in previous reports, mainly staff vacancies. There was slightly less expenditure than last year, much due to depreciation. However, expenditure this year includes that on SOHO V&S and ODD so our efficiencies are not immediately obvious. Note 4 shows the detail.

9. Income from activities (licence fees, EU income and other income) was £3,354k. Grant-in-aid (GIA) was £359k. In fact, £859k of GIA was awarded, but we did not draw down £500k as the mechanism for repaying some reserves. Income was 21% less than budgeted, 18% of which was due to not drawing down all GIA and ODD fees being subsidised. Overall income shows a very small increase from last year, due to SOHO V&S.

10. The statement of net expenditure shows net expenditure of £885k. GIA is recorded as financing, and taking that into account reduces the deficit to £526k. This has been funded from reserves.

11. Reserves stand at £2.865k at the end of March 2013, reflecting the £526k reduction since the end of last year (15.5%).

12. The reports have the same scope and requirements as last year. We have developed the Annual Governance Statement for 2012/13, based on good practice.

Debtors

13. There are now just five debtors remaining at year end, a total of £18,997. Two are from April 2012, two from January 2012 and one from November 2011. Two are NHS establishments and three are private sector bodies.

14. There have been several attempts to communicate with the establishments and solicit payment. In each case there are complications and a review is taking place to determine appropriate action. It is encouraging that the establishments have paid their fees for subsequent years.
Budget for 2013/14

15. A budget of £4.2m has been agreed for 2013/14. £3.338m is expected from the licence fees set. Devolved administrations are expected to contribute £100k and Grant-in-aid is £773k.

Financial position at 30 April 2013

16. The position after one month of the financial year has been reviewed at a high level. More detailed review will take place next month.

17. Invoices were issued to tissue for treatment sector (human application) establishments in April. Fee income is £43k less than expected (3%). There are some savings already and some contingency in the budget so this is not expected to cause difficulties, although the position will be closely monitored.

18. Expenditure is £5k more than expected in April overall, (1%). This is mainly due to profiling. Within the overall figure there are savings on staff costs due to current vacancies.

Financial risks

19. Financial risks continue to be considered on an ongoing basis. Below is a table of the 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 have identified and are managing. The strategic risk of insufficient financial resources is still considered to be low, as the HTA has sufficient reserves in hand, although the budget position in year is tight.

<table>
<thead>
<tr>
<th>Risk</th>
<th>Link to the HTA’s strategic risks</th>
<th>Mitigating actions and controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>A significant under-spend leading to a loss of stakeholder confidence in HTA’s ability to manage resources effectively.</td>
<td>Inadequate relationship management</td>
<td>Identification of the likely outturn as early as possible. Credit of unused licence fees to establishments.</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>Insufficient financial resources Failure to manage change</td>
<td>HTA undertake a periodic review of establishments and expected income. Budgets would then need to be managed to reflect income, supplemented from reserves or unavoidable costs</td>
</tr>
<tr>
<td>Risk</td>
<td>Link to the HTA’s strategic risks</td>
<td>Mitigating actions and controls</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
</tr>
<tr>
<td>Lack of prompt payment by licence fee payers affects cash flow and operations generally adversely.</td>
<td>Insufficient financial resources</td>
<td>Revenue collection will be closely monitored and the HTA’s credit control and debt collection procedures used to pursue and recover all late payments.</td>
</tr>
<tr>
<td>The HTA is required to undertake additional functions or activities not planned or costed within the approved budget.</td>
<td>Insufficient financial resources Failure to manage change Inability to carry out its statutory remit</td>
<td>The HTA’s financial management and governance arrangements will be used to identify any opportunities that may arise to make efficiencies, offset budgetary pressures and vire monies from elsewhere to fund any such initiatives or costs. Costs are closely monitored.</td>
</tr>
</tbody>
</table>
Reporting of serious incidents to the HTA

Purpose of paper

1. To explain how serious incidents at licensed establishments are reported to and handled by the HTA.

2. To provide assurance to the Authority that these systems reduce the risk of reoccurrence at reporting establishments and that there are mechanisms in place to share learning gained from analysis of incidents across the sectors, with other regulators such as the Medicines and Healthcare products Regulatory Agency (MHRA) and the Care Quality Commission (CQC), other competent authorities in Europe, and establishments themselves.

3. This paper does not review the trends in the nature of the incidents reported; this information and analysis of incidents will be covered in the Annual Review publication in July 2013.

Action

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

Decision making process to date

5. This paper follows previous discussions at the Policy and Regulatory Advisory Group (PRAG) and was considered at PRAG on 14 May 2013, ahead of the Authority meeting.
Background

6. The HTA requires licensed establishments in the Human Application (HA), Post Mortem (PM) and Transplant sectors to report certain categories of incident. The reporting requirements vary in each sector; reporting is a statutory requirement in the HA and Transplant Sectors.

7. This paper does not cover the Transplant sector. Those requirements will be reviewed with NHSBT, who manage the reporting process under a Service Level Agreement, at the end of the first year of operation. The results of that review will be reported to PRAG and the Authority.

8. The HTA has established systems for follow up of serious incidents in the HA and PM sector, which are set out in Appendices 1 and 2 of this paper.

Reporting of serious adverse events and reactions (SAEARS) in the HA sector

9. Under The Human Tissue (Quality and Safety for Human Application) Regulations 2007, establishments licensed by the HTA are required to have systems in place to report, investigate, register and transmit information about SAEARs. The HTA has an obligation as a Competent Authority to provide an annual report of SAEARS to the European Commission.

10. The aim of SAEARs reporting is to:

- reduce the occurrence and reoccurrence of adverse events and reactions;
- ensure that defective tissues and cells can be recalled rapidly from end user establishments, both in the UK and across the EU;
- ensure that licensed establishments have quality systems in place that will identify and manage deviations that could, or have, resulted in a SAEARS.

Reporting timeframe

11. Article 5 of the Commission Directive 2006/86/EC requires that SAEARs are reported ‘without delay’. In 2007, the HTA required establishments to report incidents to the HTA ‘as soon as possible’. In 2009, the HTA implemented a policy of 24 hour reporting, as a result of concerns over the time taken for establishments to report SAEARs once they were discovered. Reporting requirements are reinforced on inspection (every two years in the HA sector); consequently the HTA will have reviewed Standard Operating Procedures
11. (SOPs) for all establishments at least once since the requirement was changed.

12. Twenty four hours was considered a reasonable timeframe because:

- It met the Directive requirement for SAEARS to be reported without delay.

- It places the responsibility on establishments to ensure that events that could have implications for other establishments are reported to HTA rapidly.

- The HTA has a role in ensuring that any tissues and cells used for patient treatment are safe for use. Early reporting to the HTA enables the HTA to take immediate actions and issue urgent or rapid alerts to establishments which used the products for patient treatment, or require establishments to issue recall of any unused product as appropriate.

- Early reporting enables effective communication between the HTA and other regulators within the UK in the event that the SAEAR has implications for other regulators; for example, if the event involves a medical device, HTA would need to liaise with MHRA. In addition, early reporting enables urgent communication with Competent Authorities if the SAEARs report has implications for establishments or patients in other EU member states.

- The 24 hour time frame brings the HTA into line with other regulators such as MHRA and the Human Fertilisation and Embryology Authority (HFEA) which require incidents to be reported as soon as possible –and within 24 hours.

13. Between April 2011 and March 2013, compliance with the 24 hour reporting timeframe ranged from 0% to 93% (see Figure 1 in Appendix 3 attached). Overall compliance with the 24 hour reporting requirement improved during the period between April 2012 and March 2013 when compared with the period before it.

14. From April 2012 to March 2013 we collected data on the number of reports we received within 48 hours to establish whether establishments were just missing the 24 hour reporting timeframe. Figure 2 (Appendix 3) shows that between 62% and 93% of SAEARs were reported within 48 hours of discovery in 2012/13, and compares this with the number of reports received within 24 hours.

15. It is difficult to identify trends in the reporting data shown in these tables, other than a general improvement in the timeliness of the reporting, because the
numbers are small and can easily affected by a small number of late reports. For instance the lowest number of reports received was 3 in November 2011 with 15 being the highest in September and October 2012 and January 2013. It is also important to put these numbers into context.

16. Data provided by the European Commission demonstrates that the incidence of serious adverse events or reactions is very low. For example, the data shows that an adverse reaction will occur in approximately 0.04% cases of all tissue that is procured, tested, processed, stored and released for clinical use.

17. We have looked at reporting periods across the European Union; there is considerable variation in the required reporting times which range from 24 hours to within 15 days of discovery. However, in the case of transmissible infections, it is widely accepted that in order to prevent further infections in recipients, these incidents should be reported within 24 hours. We do not currently have any data (it is not collected by the European Commission) about compliance with reporting periods across the EU.

18. If a notification is received late, the HTA Regulation Manager assigned to the case reminds the Designated Individual (DI) of the reporting timeframe and asks for the reasons for the late reporting, reinforcing the need to report within the timeframe and the benefits to the establishment and the public of doing so. The 24 hour reporting requirement is stressed during HTA inspections and through written communication with the sector, such as the e-newsletter. The inspection will also look at whether an SOP is in place and if that SOP sets out the HTA reporting requirement.

19. Regulation Managers review incident reports when on inspection and ask establishments to report retrospectively any incidents that have occurred which fall within the SAEARs reporting criteria. This is partly to reinforce the message but also to ensure that we have accurate data about the number and types of incident occurring. To date, we have only had one incidence of an unreported SAEAR being identified on inspection.

**Reporting of HTA reportable incidents (HTARIs) in the PM sector**

20. Post mortem sector establishments have been required to report serious incidents to the HTA since 1 May 2010. We have no statutory responsibility to collect this information. However, the decision was reached to implement a reporting system, following a number of incidents that were reported voluntarily by establishments wishing to alert us of the occurrences and seeking advice on how best to deal with them. Stakeholder members of the Histopathology Working Group (HWG) provided advice on the types of
incident that we should require notification about, and have been involved in review of these since the system was introduced.

21. Until 31 March, PM Sector incidents were known as ‘Serious Untoward Incidents’ (SUIs). This term was changed to ‘HTA Reportable Incident’ (HTARIs) on 1 April 2013 at the request of the HWG and following consultation with DIs, to distinguish incidents reportable to the HTA from those that must be reported via the NHS Strategic Executive Information System (STEIS) and National Reporting and Learning System (NRLS). This change in terminology was implemented in April 2013.

**Reporting timeframe**

22. Initially establishments were asked to report incidents to the HTA ‘as soon as possible’. However, due to concerns over delays in reporting, in consultation with HWG, a timeframe for reporting was introduced and communicated to DIs in April 2011. Since then, establishments have had to report incidents within five working days of their discovery, which we continue to believe is a reasonable timeframe, for the following reasons:

- PM sector incidents do not normally pose a risk to the health or safety of living people. If there is a risk, this would be reported through the national framework for reporting serious untoward incidents.

- Unlike the HA sector, the HTA does not have a role in ensuring patient safety, as is the case with SAEARs, which may require immediate attention by the HTA, for example, the issue of a regulatory alert or communication with another Competent Authority.

- Five days allows sufficient time for the establishment to take immediate steps and form an initial view about potential causes, which can be considered by the HTA in its response.

- Staff that may be involved in incidents include nurses, porters and mortuary staff, who work outside normal working hours. It may therefore take a day or two to establish even brief details about the circumstances leading to the incident.

- Allowing five days for reporting ensures that the reporting requirement does not needlessly interfere with the initial actions being taken to address the incident and the care of the bereaved, which should be the establishment’s first priorities.
23. Over the past two years, compliance with the five working day reporting timeframe has ranged from 55% to 83% (see Figure 3 on page 8). As with late notification of SAEARs, if a notification is received beyond the five day timeframe, the Regulation Manager assigned to the case reminds the DI of the reporting timeframe and asks for the reasons for the late reporting, reinforcing the need to report within the timeframe and the benefits to the establishment of doing so. Where appropriate, for example, if this is not the first incidence of late reporting, the matter is escalated at the HTA and/or with the establishment.

24. There are several reasons for late reporting. We believe there is a correlation between the level of formality of reporting requirements (as set out in local SOPs) and late reporting; in some cases, there may only be a realisation of due process when an incident occurs for the first time. We are also aware that delays are sometimes caused by the establishment’s decision to begin investigating and identify corrective actions prior to reporting it to the HTA, which may, to some degree, be linked to the earlier point about a lack of understanding locally regarding reporting requirements (and sufficient appropriate detail in operating procedures/staff training). On inspection we reinforce the need that early reporting is key and the detail can follow later. A further reason for late reporting may be reluctance to allow less senior staff (i.e. Persons Designated) to report incidents, who are therefore required to wait for the availability of the DI.

25. Late reporting is factored into an establishment’s risk rating. The five working day reporting requirement is stressed during HTA inspections and through written communication with the sector, such as the e-newsletter. However, as the graph illustrates, there is still some late reporting and we need to consider what more we could do raise awareness and improve compliance. The answer may lie in communicating more effectively about the benefits of reporting, i.e. what the HTA can do to help when an HTARI occurs, so that the establishment sees it as a helpful intervention rather than a burdensome regulatory requirement.

26. We have recently been informed that the AAPT has posted a new test on changes to the HTA incident reporting system on its on-line learning resource ‘Read, Test and Reflect’ (RTR), which is available to around 300 APTs registered with the Association (a little less than half of APTs working in mortuaries in the UK). Correct completion of the test provides the APT with CPD credits and there is the option to complete a reflective learning sheet to gain additional credits. This should help improve reporting rates and is a good example of the excellent and constructive working relationships we have with
PM sector stakeholders.

27. Since October 2012, Regulation Managers have been reviewing incident reports on inspection and asking establishments to report retrospectively any incidents that have occurred since 1 May 2010 which fall within the HTARI reporting criteria. This is partly to reinforce the message but also to ensure that we have accurate data about the number and types of incidents occurring. It is also in line with the approach taken in relation to SAEARs. Since late October, we have received eight reports of HTARIs discovered by Regulation Managers on inspection.

28. If the Regulation Manager has reviewed the action that was taken at the time of the incident whilst they were on inspection and considers it appropriate, we do not repeat the exercise. However, for completeness, we request a copy of the internal investigation report and evidence of actions taken as well as the notification itself.

29. Since the reporting requirement began, escalation procedures have been strengthened to ensure follow up reports are submitted without undue delay. This has informed a new policy on dealing with DIs who fail to respond to requests for information. Compliance with the reporting periods for the last two business years is shown in figure 3, Appendix 3. As for SAEARs it is difficult to draw conclusions from the data because of the small numbers of incidents involved. Setting this into context, in 2011 (the latest data available), there were 222,371 deaths reported to coroners, of which approximately 94,000 (42%) were subject to a post mortem examination.

Sharing learning (HA and PM sectors)

30. To date, the learning gained from investigation of HTARIs and SAEARs has been disseminated in annual publications to the sector, via the e-newsletter and to DIs on inspection. As well as facilitating robust and auditable record keeping of communications and document submissions from notification through to conclusion of the incident investigation, the on-line reporting system enables greater analysis of the data, in particular trends in root causes, which will improve our ‘lessons learned’ and the feedback we communicate to the sector. It should also help reduce the likelihood of incidents happening again.

31. The HTARI team and SAEARs team meet monthly to discuss new cases, difficult issues and any data trends that have been identified. As a result of these meetings, information is disseminated about the incidents to Regulation Managers through feedback and discussion at fortnightly meetings and
guidance documents. The Regulation Directorate is currently working with colleagues in the Communications and Public Affairs Directorate on the development of sector-specific 'advice notes' to be disseminated to DIs via the HTA portal. We plan to pilot this in the PM sector later this year.

**Reporting Periods (HA and PM sectors)**

32. As described above the number of establishments reporting incidents within the timeframe is variable quarter on quarter but has an upward trend. Whilst extending the period may increase the number of establishments able to report on time we believe that this may result in a reduction of incidents being reported to us within the existing periods. This could mean delayed reporting of incidents which have an impact on patient or public safety or on public confidence. It may also give the perception that the HTA believes the incidents are not serious. For those reasons we do not believe that we should change the reporting periods.

**Follow up (HA and PM sectors)**

33. That leaves the question of how we deal with establishments who do not report within the required timescale. We have described how we follow-up late reports and communicate the timelines with establishments. This may involve escalation to the Corporate License Holder, Chief Executive or Board of the establishment. We also take into account late submissions when scheduling inspections; repeated late submissions may result in a non-routine inspection or in an inspection being brought forward. This enables us to tackle the late reporting in the wider context of the establishment’s activities and, if necessary, to take any regulatory action.
Appendix 1: Investigation of SAEARS

1. Following notification of a SAEARS, the case is assigned to a Regulation Manager who tracks and reviews all stages of the establishment’s investigation. A key aspect of this review is to ensure that the corrective and preventative actions taken by the establishment are sufficiently robust to reduce the likelihood of recurrence. In reviewing the initial information provided, the Regulation Manager considers the following key points:

- Are there any implications for other patients?
- What immediate corrective and preventative actions have been taken?
- Does the incident have potential consequences for the supply of tissues and cells in the UK?
- Are there any implications for other recipients in other countries?
- Is a Rapid Alert for Tissues and Cells (RATC) required to alert other member states?
- Is a full and thorough investigation being conducted?
- Do any other regulators need to be communicated with e.g MHRA
- Is the event likely to generate media interest.

2. The Regulation Manager contacts the person who reported the SAEAR either by email or by phone to seek clarification as required. It should be noted that the Regulation Manager investigating the SAEARs will follow the investigation steps outlined below under the HTARI section paragraphs 6, 7 and 9.

3. The vigilance tools used and procedure used to grade and review SAEARs is guided by recommendations issued by the EU funded EUSTITE (EU standards and training for the inspection of tissue establishments) project and the SOHO V&S (Substances of human origin Communications)

4. – vigilance and surveillance) project.

5. The vigilance tools include:

- Criteria for reporting Serious Adverse Events (SAEs)
- A severity grading system for Serious Adverse Reactions (SARs) with guidance on which level to report
- An imputability grading system for SARs which assesses the probability that an SAR can be attributed to the tissue or cells used for patient treatment or an adverse reaction in a donor can be linked to the donation process
- An impact grading system which is similar to a risk management tool and takes into account the probability of recurrence and the consequences of recurrence. The grading is colour coded – green, amber and red depending on the impact of the respective SAR or SAE.
6. Once the establishment has submitted a follow up report to the HTA the Regulation Manager updates the impact tool in order to ensure that the steps taken by the establishment reduces the probability of recurrence and/or the consequences of recurrence before closing the SAEARs. All SAEARs are recorded as cases and linked to the respective licensed establishment in the HTA’s licence management system.

7. Occasionally, a non-routine inspection follows receipt of a SAEARs notification, either at the request of the establishment or because the Regulation Manager and Head of Regulation believe there is a risk to patient safety or public confidence. It is unlikely that we would undertake a non-routine inspection based on delayed reporting only, but this may be a factor in the decision making.
Appendix 2: Investigation of HTARIs

Initial response

1. Incidents are managed by a team of Regulation Managers and a Regulation Officer, overseen by a Head of Regulation.

2. On receipt, a new PM incident notification is assigned to a Regulation Manager, who carries out an initial risk assessment, rating the incident as high, medium or low. This informs how we deal with the incident, the level of HTA involvement and the support and advice provided to the establishment, and is documented in the SOP for managing HTARIs. The Communications and Public Affairs Directorate will be notified if the Regulation Manager feels that the matter may be the subject of media or public interest.

3. In reviewing the initial information provided, the Regulation Manager considers the following key points:
   - What immediate corrective and preventative actions have been taken?
   - Has the deceased patient’s family been told? If not, why not?
   - Is the family likely to make a formal complaint or approach the media?
   - Are there early indications about the cause of the incident?
   - Is a full and through investigation being conducted?

4. It is not uncommon for the Regulation Manager to respond with a list of questions to get a fuller picture of what happened. However, if sufficient initial information has been provided, the Regulation Manager contacts the DI to agree a deadline by which the follow up report should be provided. This is normally within two months, which allows reasonable time for the establishment to carry out a root cause analysis and identify any corrective or preventative actions that will be taken as a result.

5. Occasionally, a non-routine inspection follows receipt of a HTARI notification, either at the request of the establishment or because the Regulation Manager and Head of Regulation believe there is a risk to other deceased persons or a risk to public confidence. It is unlikely that we would undertake a non-routine inspection based on delayed reporting only, but this may be a factor in the decision making.

Investigation

6. The responsibility for investigating a serious incident lies with the establishment where the incident occurs. They are required to submit a follow up report
outlining the root causes and actions taken or planned to mitigate the risk of a similar incident occurring again.

7. On receipt, follow up reports are assigned to the same Regulation Manager who handled the initial notification. In reviewing the final report the Regulation Manager will consider the following points:

- Has the incident been escalated appropriately?
- Have all avenues of investigation been explored?
- Have all root causes been identified?
- Are the actions that have been identified suitable to address the risk of reoccurrence?
- Have the actions been completed or are they scheduled with deadlines?

8. If the Regulation Manager is satisfied with the establishment’s internal investigation, the case is closed and a letter sent to the DI giving a brief outline of the incident, the root causes and the actions identified. A HTARI is only considered closed when the HTA is satisfied: (i) that the investigation has been thorough and considered all possible root causes; and (ii) that the actions identified address the root causes and mitigate the risk of the incident happening again.

9. If the follow up report and actions taken by the establishment fall short of HTA standards, the Regulation Manager will set up an agreed corrective and preventative action (CAPA) plan which is managed through CRM, and ask the establishment to provide evidence of completion of all actions. If the Regulation Manager and Head of Regulation have serious concerns about the establishment’s management of an incident, the HTA may arrange a non-routine inspection of the licensed premises. Any actions which are still outstanding at the conclusion of the establishment’s investigation will also be tracked in CRM through to completion. This ensures that action is taken following an HTARI to prevent repeats of the same incident.
Appendix 3: Statistics

Fig 1: SAEARs reported within 24 hours of discovery April 2011 to March 2013

![Chart showing SAEARs reported within 24 hours]

Fig 2: A comparison of SAEARs reported within 24 hours with total SAEARs reported within 48 hours April 2012 to March 2013

![Chart comparing 24-hour and 48-hour SAEAR reporting]
Fig 3: HTARIs reported within five working days of discovery, Q1 2011/12 – Q4 2012/13 (not including near misses and non-HTARIs)

Excludes incidents identified on inspection not reported within the required timeframe.
Authority paper

Date 28 May 2013  Paper reference HTA (28/13)
Agenda item 11  Author Allan Marriott-Smith

Independent Assessor Survey Results

Purpose of paper

1. The purpose of this paper is to provide the Authority with the high level results of the Independent Assessor (IA) Survey which was undertaken during April 2013.

Action

2. The Authority is asked to note the content of the paper and provide any comments.

Decision-making process to date

3. SMT agreed in early 2012 that a survey would be undertaken of Independent Assessors during the latter part of the 2012/13 business year. This was reported to the Authority in February 2012.

4. The Audit Committee received an update on the risks to the IA system and the plans for the survey at its meeting in November 2012.

5. SMT reviewed the initial survey results at its meeting on 9 May and approved the paper for the Authority.

Background

6. IAs undertake interviews on the HTA's behalf in living organ donation cases and fulfil a vital role in the overall living organ donation programme. Without IA interviews, living donations cannot lawfully be approved to proceed.
7. The majority of IAs are volunteers who work at a hospital with a Transplant Unit. They are required not to have any link to the transplant programme and are usually recruited by adverts posted on intranet sites and on notice boards by living donor coordinators (LDCs).

8. Pressure to make cuts and increase efficiency continues to grow in the NHS. In early 2012, the HTA began to receive feedback from some IAs that their home departments are unable to be as flexible as they once were in allowing them time to carry out IA interviews.

9. The HTA registered this risk in February 2012 and committed to undertaking further work on establish how likely that this risk is to materialise. The Audit Committee received an update in November 2012 that the IA system appeared to be stable on the basis that the HTA had recently recruited six new IA’s and received no IA resignations in the previous twelve months. In addition, all those invited to undertake enhanced IA training had agreed to do so.

10. The IA survey was launched on 8 April and closed on 30 April. It aimed to deliver a comprehensive picture of the IA system which will allow the HTA to assess the general condition of the system, identify any risks to its continued successful operation, and identify any areas for improvement.

11. In all, 83 of 131 (63 per cent) of IAs responded to the survey. The main body of the survey allowed the IAs to complete check boxes to record their answers. There were opportunities throughout the survey to provide further free text comment. The headline results, comprising the check box responses to key questions are included in the Annex to this paper.

**Next steps**

12. Further analysis of the text box responses will be undertaken by the end of May.

13. This analysis along with any proposals for action will be put to SMT in June, and any agreed actions will be added to the business plan for 2013/14.

14. IAs and the Authority will subsequently be provided with details of the full findings and the agreed actions.
### IA questionnaire

1. **How long have you been an IA?**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than a year</td>
<td>7.2%</td>
<td>6</td>
</tr>
<tr>
<td>1 or 2 years</td>
<td>16.9%</td>
<td>14</td>
</tr>
<tr>
<td>3 or 4 years</td>
<td>31.3%</td>
<td>26</td>
</tr>
<tr>
<td>5 or more years</td>
<td>44.6%</td>
<td>37</td>
</tr>
</tbody>
</table>

- answered question: 83
- skipped question: 0

2. **Do you receive any payment specifically for undertaking the IA role?**

<table>
<thead>
<tr>
<th>Response</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>24.1%</td>
<td>20</td>
</tr>
<tr>
<td>No</td>
<td>75.9%</td>
<td>63</td>
</tr>
</tbody>
</table>

- answered question: 83
- skipped question: 0

3. **Have you attended any equality and diversity training in the last two years?**

<table>
<thead>
<tr>
<th>Response</th>
<th>Response Percent</th>
<th>Response Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>65.4%</td>
<td>53</td>
</tr>
<tr>
<td>No</td>
<td>34.6%</td>
<td>28</td>
</tr>
</tbody>
</table>

- answered question: 81
- skipped question: 2
## 4. To what extent do you agree with the following statements? Please feel free to elaborate in the comments section.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Disagree</th>
<th>Tend to disagree</th>
<th>Tend to agree</th>
<th>Agree</th>
<th>Rating Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have enough time to prepare for an interview when a case has been referred to me.</td>
<td>3.7% (3)</td>
<td>4.9% (4)</td>
<td>31.7% (26)</td>
<td>59.8% (49)</td>
<td>82</td>
</tr>
<tr>
<td>The HTA provides me with all the information I need to prepare for an interview.</td>
<td>0.0% (0)</td>
<td>3.7% (3)</td>
<td>20.7% (17)</td>
<td>75.6% (62)</td>
<td>82</td>
</tr>
<tr>
<td>The clinical team provide me with all the information I need to prepare for an interview.</td>
<td>0.0% (0)</td>
<td>2.4% (2)</td>
<td>28.0% (23)</td>
<td>69.5% (57)</td>
<td>82</td>
</tr>
<tr>
<td>I have access to adequate resources and facilities to undertake interviews.</td>
<td>2.4% (2)</td>
<td>8.5% (7)</td>
<td>19.5% (16)</td>
<td>69.5% (57)</td>
<td>82</td>
</tr>
<tr>
<td>The HTA’s online submission system is easy to access and use.</td>
<td>1.2% (1)</td>
<td>2.4% (2)</td>
<td>23.2% (19)</td>
<td>73.2% (60)</td>
<td>82</td>
</tr>
<tr>
<td>I have difficulties fitting in my duties as an IA alongside my other responsibilities.</td>
<td>50.0% (41)</td>
<td>20.7% (17)</td>
<td>22.0% (18)</td>
<td>7.3% (6)</td>
<td>82</td>
</tr>
</tbody>
</table>

Comments: 37 answered question, 82 skipped question
5. I would describe my caseload of IA interviews as

<table>
<thead>
<tr>
<th>Response</th>
<th>Percent</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too light</td>
<td>13.6%</td>
<td>11</td>
</tr>
<tr>
<td>Just right</td>
<td>85.2%</td>
<td>69</td>
</tr>
<tr>
<td>Too heavy</td>
<td>1.2%</td>
<td>1</td>
</tr>
</tbody>
</table>

Comments

answered question 81
skipped question 2

6. In the last twelve months have you been asked to consider discontinuing your IA role?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percent</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>3.7%</td>
<td>3</td>
</tr>
<tr>
<td>No</td>
<td>96.3%</td>
<td>79</td>
</tr>
</tbody>
</table>

answered question 82
skipped question 1

7. In the last twelve months, have you considered discontinuing your IA role?

<table>
<thead>
<tr>
<th>Response</th>
<th>Percent</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>19.8%</td>
<td>16</td>
</tr>
<tr>
<td>No</td>
<td>80.2%</td>
<td>65</td>
</tr>
</tbody>
</table>

answered question 81
skipped question 2
8. To what extent do you agree with the following statements Please feel free to elaborate in the comments section.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Disagree</th>
<th>Tend to disagree</th>
<th>Tend to agree</th>
<th>Agree</th>
<th>Rating Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>I know how to access support from the HTA about my role if I need it.</td>
<td>0.0% (0)</td>
<td>1.2% (1)</td>
<td>12.2% (10)</td>
<td>86.6% (71)</td>
<td>82</td>
</tr>
<tr>
<td>The right support has been available from the HTA when I've needed it.</td>
<td>0.0% (0)</td>
<td>2.4% (2)</td>
<td>13.4% (11)</td>
<td>84.1% (69)</td>
<td>82</td>
</tr>
<tr>
<td>I feel confident approaching the HTA for guidance.</td>
<td>0.0% (0)</td>
<td>1.2% (1)</td>
<td>11.0% (9)</td>
<td>87.8% (72)</td>
<td>82</td>
</tr>
<tr>
<td>I find the IA bulletin a useful resource.</td>
<td>0.0% (0)</td>
<td>6.1% (5)</td>
<td>37.8% (31)</td>
<td>56.1% (46)</td>
<td>82</td>
</tr>
<tr>
<td>The IA bulletin keeps me sufficiently informed about changes and developments that I need to know about.</td>
<td>0.0% (0)</td>
<td>6.2% (5)</td>
<td>28.4% (23)</td>
<td>65.4% (53)</td>
<td>81</td>
</tr>
<tr>
<td>I find the HTA website page for Independent Assessors a useful resource.</td>
<td>1.3% (1)</td>
<td>11.3% (9)</td>
<td>47.5% (38)</td>
<td>40.0% (32)</td>
<td>80</td>
</tr>
<tr>
<td>I feel I have further training needs to be met to undertake my IA role effectively.</td>
<td>23.5% (19)</td>
<td>49.4% (40)</td>
<td>21.0% (17)</td>
<td>6.2% (5)</td>
<td>81</td>
</tr>
<tr>
<td>I would like the opportunity to attend enhanced training for IAs.</td>
<td>20.8% (16)</td>
<td>11.7% (9)</td>
<td>31.2% (24)</td>
<td>36.4% (28)</td>
<td>77</td>
</tr>
<tr>
<td>I would benefit from more opportunities to share experience and knowledge with other IAs.</td>
<td>2.5% (2)</td>
<td>21.3% (17)</td>
<td>48.8% (39)</td>
<td>27.5% (22)</td>
<td>80</td>
</tr>
<tr>
<td>I find the annual IA reaccreditation process beneficial.</td>
<td>1.2% (1)</td>
<td>12.3% (10)</td>
<td>29.6% (24)</td>
<td>56.8% (46)</td>
<td>81</td>
</tr>
</tbody>
</table>

Comments 35

answerered question 82

skipped question 1
Regulatory Activity Report Q4

Purpose of paper

1. This paper provides a high-level summary to the Authority of how the HTA manages information relating to actual or potential breaches of the regulatory framework, both internally and externally. This report provides information on:

   a. **Critical shortfalls**: any critical shortfalls identified against licensing standards;

   b. **Investigations**: how the HTA deals with information it receives about breaches, including investigation of allegations from external sources, regulatory action panels convened, and management of information through routine and non-routine inspections;

   c. **Legal activity**: legal activity associated with the management of breaches, including issuing legal notices and responding to requests to hear representations or appeals;

   d. **Incidents**: serious incidents routinely reported to the HTA from licensed establishments in the post mortem and human application sectors; and

   e. **Other regulatory activity**: this section of the report describes regulatory activities undertaken by the HTA which fall outside of categories (a)-(d) above. This could include, for example, measures which are taken to address failures to comply with General Directions, or taken as a result of repeated regulatory breaches by an establishment.
Decision-making to date

2. SMT reviewed the content of the report and suggested amendments at its meeting on 2 May 2013.

3. The Policy and Regulatory Activity Group (PRAG) scrutinised the report at its meeting on 14 May 2013. The paper is provided here for information.

Critical shortfalls

4. Critical shortfalls against licensing standards are those considered to be of such significance that the HTA would normally expect licensable activities to cease immediately, until that shortfall was addressed.

5. In quarter four (Q4), no shortfalls against licensing standards were assessed as critical.

6. There were no shortfalls assessed as critical in the 2012 / 13 business year.

Investigations

7. There were three new investigations in Q4. There were three ongoing investigations from quarter three (Q3). Of these, two were closed in Q4. The total number of investigations going into quarter one (Q1) 2013 / 14 is four.

Investigation one

8. In late Q3, the HTA received a phone call from a member of the public about an alleged incident which took place at a mortuary. The HTA contacted the designated individual (DI) of the establishment. The DI explained that the establishment had already been made aware of the allegation by the same individual who had contacted the HTA. As that person presented only limited information of the alleged incident to the hospital, The Trust decided not to launch a formal internal investigation into the matter. The DI also said that the person making the allegation had been invited to provide further information, but had not done so. The DI has spoken with staff at the mortuary, who were not aware of any incident of the nature described in the allegation.

9. The HTA has closed its investigation. Should further information become available, the HTA may reopen its investigation. The HTA wrote to the DI and the person who made the original allegation to inform them that the investigation is closed. The HTA encouraged the individual to contact the Trust, if they had further information about the allegation. No response has been received.
Investigation two

10. In Q4, the DI of a licensed establishment in the human application sector contacted the HTA about the licensing status of another UK-based organisation. The DI reported that he was aware UK dentists have been contacted by this organisation regarding the procurement of teeth for processing in another country.

11. The organisation was not licensed by the HTA. The organisation is based in Guernsey, which is an area outside the HTA’s remit. The processing organisation is based in Switzerland. The investigation is on-going and both organisations will be contacted to inform them of the regulatory requirements around procurement in the UK. The HTA will request clarification regarding potential licensable activities in the UK. An update will be provided in Q1 2013 / 14.

Investigation three

12. In Q4 an allegation was received from a former DI at a licensed establishment in the research sector. The allegations included a number of concerns relating to research governance, and possible breaches of the regulatory requirements for human tissue research.

13. The HTA asked for further information. The DI responded with the results of an internal investigation. This identified a number of non-compliances, but no evidence of intention to act wrongly by staff members.

14. The HTA requested further clarification. The DI responded within the required timeframe confirming a number of control mechanisms had been implemented to prevent similar incidents happening in future.

15. The establishment’s own investigation identified the need for an action plan to improve governance under the licence. The DI confirmed this would be completed by May 2013 and a copy provided to the HTA. Once this information is received and reviewed, a decision will be made about further steps. An update will be provided in Q1 2013 / 14.
Update on ongoing investigations

Update one

16. In Q3, an allegation was received from a licensed establishment that three other establishments were distributing or storing human tissue for patient treatment without the appropriate HTA licence. Two of the companies were involved in product sales. The third was a patient treatment centre, not involved in distribution. The HTA reviewed the product catalogue from the first company, involved in product sales. There were no products that appeared to be of human origin on offer. Synthetic products were offered. The second company was related to the first company, with direct links between websites and management. The HTA contacted all three companies and received written confirmation from the implant centre and the first distributing company that they were not carrying out the alleged activities. The third organisation, which is related to the company involved in distribution of products has yet to reply. The HTA is following this up. An update will be provided in Q1 2013 / 14.

Update two

17. The quarter two (Q2) RAR described an investigation by the Dutch Competent Authority (CA) into a UK-based establishment’s procurement arrangements for cord blood samples in the Netherlands.

18. The establishment had not breached HTA requirements. In Q4 the Dutch CA sent an email to the establishment, copied to the HTA, to confirm no regulatory action would be taken against the establishment. The investigation is now closed.

Update three

19. The Q2 RAR referred to an investigation by the German CA into material procured without consent in the Ukraine and imported into the EU by a German company. There was no action necessary by the HTA in the UK.

20. The Q3 RAR reported that the HTA observed an inspection of the distributor’s site, in Germany. The German CA found ‘critical findings’ which require rectification. These findings related to a SAEARs reporting system and traceability. The German CA asked the establishment to take action in respect to these findings and provide the German CA with further information. Once a response is received, the German CA will share a final report with the HTA. An update will be provided in Q1 2013 / 14.

21. A sector-specific breakdown of investigations during the past six quarters is given in Table 1 (Annex One).
Regulatory Decisions

22. Following review of the HTA’s decision making processes, a new system for making regulatory decisions is in place. This was described in the RAR for Q2.

23. Five Regulatory Decision (RD) meetings were held during Q4 to consider the need for regulatory action.

24. The Q3 RAR referred to an RD meeting held to review the suspension of an establishment’s processing activity and conditions on its storage activity. In Q4, four further RD meetings were held for this establishment and for the establishments it is now contracting with to take on storage and processing.

25. Following these RD meetings the establishment has revoked its processing and storage license. It now only undertakes procurement activity. Conditions are in place to ensure that the tissue is held in quarantine and information about its processing activity is made available if the tissue is released. Similar directions are in place for the other establishment which is storing the tissue. Processing at the other establishment has not started. The establishment which will undertake the processing has prepared a Preparation Process Dossier and submitted this to the HTA.

26. The fifth RD meeting held in Q4, followed information received from the German CA. The German CA received information from the US Food and Drug Administration (FDA) that a US company had received an FDA warning letter about the quality and safety of its material. The company has a UK-based office licensed to import and distribute material from the US. The HTA’s Chief Executive Officer (CEO) decided to:

- suspend the import activity on the licence;
- require the UK licensed establishment to recall all material sent to its end-users; and
- issue a regulatory alert.

27. The decision was made as the CEO felt the HTA could not be assured of the quality and safety of the tissues and cells distributed in the EU. The CEO set a deadline of 5 April 2013 to account for the practicalities of recalling material during the Easter long weekend. The DI was informed of the decision.

28. The HTA asked the FDA how it intends to deal with the response provided to the warning letter by the US company. The HTA asked the Medicines and Healthcare products Regulatory Agency to confirm whether it had any dealings with the UK licensed establishment. Further RD meetings have
been held in Q1 2013 / 14 to review the decision. An update will be provided in Q1.

29. A sector-specific breakdown of Regulatory Action Panels (RAPs) and RD meetings convened during the past six quarters is given in Table 2 (Annex One).

Non-routine site-visit inspections

30. Two non-routine site-visit inspections took place in Q4.

Non-routine inspection one

31. The first non-routine inspection was of a post mortem establishment. This was in response to a serious untoward incident (SUI) reported by the establishment. The corrective and preventive actions agreed with the HTA following the establishment’s internal investigation of the incident were found to have been fully implemented. The Regulation Managers conducting the inspection were satisfied that these actions mitigated the risk of a similar incident happening again.

32. The establishment was found to have met all HTA standards. The HTA gave advice to the DI about replacement of the DI following transfer of the establishment’s services.

Non-routine inspection two

33. The second non-routine inspection was also of a post mortem establishment. This inspection was classified as non-routine as it was triggered by a major change to premises as post mortem activities had recently moved to a new mortuary built within the same hospital site. This was the second inspection of the establishment. The establishment was found to have met all standards.

34. A sector-specific breakdown of non-routine inspections during the past six quarters is given in Table 3 (Annex One).

Legal notices

35. Legal notices were issued to two establishments during Q4.

36. The Q1 RAR described Directions issued to an establishment to address major shortfalls. Following an RD meeting described in paragraphs 24 to 25, above, a number of Directions were issued to the establishment. Legal notices required:
• suspension of processing activity;
• a variation on the licence to ensure all material was quarantined;
• proposed conditions on any future release of material;
• restrictions on the use of testing facilities; and
• contacting clients about the impact of Directions on quarantine and labelling requirements to restrict release of samples.

37. The DI sent preliminary information on steps taken to validate processes, including an unsigned agreement for processing and storage by another HTA licensed establishment. The establishment confirmed that letters were sent to its clients about the suspension of processing activities. By December, the processing laboratory was decommissioned and all technology and samples were transferred to another HTA licensed establishment. The establishment made representations which it subsequently withdrew, referred to in paragraph 45 below.

38. Following the RD Meeting described in paragraphs 24 to 25, above, a decision was made to issue Directions to a licensed establishment receiving material from the establishment described in paragraphs 36 and 37.

39. The HTA issued the following Directions:

• transferred cryoboxes will be placed within over-wrap bags which have been validated for use in liquid nitrogen storage systems;
• no transferred tissues and cells may be transferred to another organisation or released for patient treatment without prior written permission from the HTA;
• the receiving establishment must complete a risk assessment to assess risk to other samples already stored; and
• the receiving establishment must contact the HTA in the event any client requests release of tissue and cells which were held in the same storage area as the transferred tissues and cells.

40. The HTA also issued a Direction to the receiving establishment, requiring any client records of tissues and cells stored by the establishment sending the material, to be marked with the following statement: “The Human Tissue Authority has been unable to assure itself of the quality of processing and testing used on this sample. Any intended use must take into account these requirements and a risk assessment must be undertaken prior to use”.

41. The receiving establishment has informed the HTA the above Direction has been implemented. A copy of the Directions was provided to both establishments.
42. Paragraph 26 of this RAR describes an RD meeting to consider a response to information received from the German CA about a US company. At the meeting the CEO decided to issue Directions to the company. These were:

- suspend the import activity on the licence; and
- require the UK licensed establishment to recall all material sent to its end-users.

43. The Q4 2011 / 12 RAR described Directions issued to an establishment which had distributed non-CE marked blood spot cards to clients for serology testing. The Q1 2012 / 13 RAR confirmed the establishment had complied with the Directions by submitting test results for the majority of donors. Two donors have not provided samples for repeat test results and these samples are stored in quarantine, and marked ‘not to be released’, in line with the Directions.

44. Since Q4 of 2011 / 12, the HTA has been in contact with the DI who has confirmed that further verbal communication has taken place with clients who have not yet provided a repeat blood sample. These clients have been advised that the samples will remain in the non-compliant tank, designated ‘not for clinical use’. The DI confirmed the establishment will not dispose of these samples unless it receives permission from the client. The HTA intends to issue further Directions listing the samples that are outstanding and directing that these samples remain in quarantine – ‘not for clinical use’ until such times as the blood spot card is CE marked or a repeat blood sample for donor virology testing is provided. An update will be provided in the Q1 2013 / 14 RAR.

Representations or appeals

45. The Q3 RAR referred to a notification of intention to make a representation. In Q4 the establishment referred to in paragraph 37 reached an agreement with the HTA about conditions on its licence and discontinued its representations. No new representations were made in Q4. No appeals have been made in the past six quarters.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

HTA Reportable Incidents (HTARIs) reported in the post mortem sector

HTARIs reported in Q4

46. There were 19 HTARI notifications received in Q4. This is a decrease on Q3 (25 notifications). The non-HTARIs and near misses are not included.

47. In Q4, 13 HTARI notifications (72%) were received within five working days of the incident occurring. One of the 19 HTARIs was excluded from this calculation as details about time of discovery was not available. Three of the five HTARIs reported late were reported at 8, 9 and 11 working days. One was reported after 6 weeks. This last HTARI was raised immediately through the establishment’s internal reporting system. Another incident was reported seven months after the incident occurred. This extended time lapse was due to a new DI reporting the incident after coming into the post. The notification rate within the correct timeframe can be compared with 56% in Q3, 63% in Q2 and 73% in Q1.

48. A breakdown by category of HTARIs during the past six quarters is given in Table 5 (Annex One).

Ongoing HTARIs from previous quarters

49. An HTARI is considered closed when the HTA is satisfied the incident has been thoroughly investigated by the establishment, and appropriate corrective and preventive actions taken. The HTA normally expects to receive an establishment’s internal investigation report within two months of the initial HTARI notification.

50. The Q3 RAR referred to one outstanding HTARI from Q2. The establishment had not yet submitted its final report as it required more time to conduct a wider search of its holdings. This remains outstanding. The responsible RM followed up with the establishment and was advised in Q4 that the root cause analysis has been drafted; the RM will monitor progress until the investigation is concluded. There were seven outstanding HTARIs from Q3. 72% of HTARIs raised in Q3 were also closed in Q3.
<table>
<thead>
<tr>
<th>Number of HTARIs</th>
<th>HTARI category</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Accidental damage to a body</td>
</tr>
<tr>
<td>5</td>
<td>Any other incident that could result in adverse publicity that may lead to damage in public confidence</td>
</tr>
<tr>
<td>1</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>
</tr>
<tr>
<td>1</td>
<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>
</tr>
<tr>
<td>1</td>
<td>Discovery of an organ or tissue following PME and release of body</td>
</tr>
<tr>
<td>4</td>
<td>Release of the wrong body</td>
</tr>
<tr>
<td>1</td>
<td>Serious security breach</td>
</tr>
<tr>
<td>1</td>
<td>Viewing of the wrong body</td>
</tr>
</tbody>
</table>

Table 1: Number of HTARIs in the PM sector reported to the HTA in Q4

Serious adverse events and adverse reactions (SAEARs) reported in the patient treatment sector

SAEARs reported in Q4

51. Thirty-five SAEAR notifications (31 serious adverse events (SAEs) and four serious adverse reactions (SARs)) were received in Q4 (Table 2). Notifications of incidents which HTA has not categorised as a SAEAR are excluded from this table. A breakdown by category of SAEARs during the past six quarters is given in Table 6 (Annex One).
24 hour reporting requirement for SAEARs

52. It is a mandatory requirement for an initial notification of a SAE or SAR to be given to the HTA within 24 hours of the discovery of the event or reaction by the licensed establishment. The HTA reinforces the 24-hour reporting requirement when it inspects establishments in the human application sector. As with HTARIs, repeated late reporting of SAEARs is factored into an establishment’s risk rating in the HTA CRM licensing system. Of the 35 SAEARs reported in Q3, notification was received by the HTA:

- within 24 hours of discovery in 29 instances (83%). This can be compared with 63% for Q3, 51% for Q2 and 68% for Q1; and
- within 14 days of the date of discovery in five instances (14%).

53. There was one SAE reported 84 days after discovery in Q4. The DI was not aware this was reportable and reported it the same day as making an on-time report for another SAE.

<table>
<thead>
<tr>
<th>Number reported</th>
<th>Activity/type of SAEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Procurement</td>
</tr>
<tr>
<td>4</td>
<td>Processing</td>
</tr>
<tr>
<td>5</td>
<td>Storage</td>
</tr>
<tr>
<td>2</td>
<td>Distribution</td>
</tr>
<tr>
<td>1</td>
<td>Preservation</td>
</tr>
<tr>
<td>1</td>
<td>Materials</td>
</tr>
<tr>
<td>6</td>
<td>Other¹</td>
</tr>
<tr>
<td>1</td>
<td>Donor reaction²</td>
</tr>
<tr>
<td>3</td>
<td>Recipient reaction³</td>
</tr>
</tbody>
</table>

Table 2: Numbers of serious adverse events and adverse reactions in the human application sector reported to the HTA in Q3. ¹SAEs in this category relate to clumping of PBSCs, leakage of cells, expiry date discrepancies, liver inflammation indicated in donor post corneal transplant and a dropped frozen infusion bag.²The SAR in this category related to an allergic reaction. ³The SAR in this category related to two primary graft failures and neurotoxicity

Ongoing SAEARs reported in previous quarters

54. A follow-up report must be submitted to the HTA upon completion of the establishment’s internal investigation into the SAE or SAR. The HTA would normally expect a follow-up report to be submitted within 90 days of the initial notification of the SAE or SAR.

55. There are two outstanding SAEARs follow-up reports due from SAEARs reported in Q2. There is one outstanding SAEAR from Q3. RMs have contacted DIs for a progress report on these.
SAEARs reported in the organ donation and transplant (ODT) sector

56. The Q3 RAR describes NHSBT’s assisted function, under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, to report SAEARs in the ODT sector. The Q3 RAR describes the service level agreement (SLA) in place between the HTA and NHSBT which includes the need for NHSBT to deliver reports on time.

57. NHSBT notified HTA of 12 ODT SAEARs (nine SAEs, three SARs) during Q4. One of these concerned an incident which occurred before the licensing period. Of the remaining 11 notifications, three were made to NHSBT within 24 hours of the event or reaction being discovered. The reporting times for the other SAEARs were 2, 2, 3, 3, 5, 7 and 11 days after the transplant event or reaction was discovered.

58. NHSBT has reported to the HTA outside of the next working day timeframe on five occasions in Q4. One SAEAR was reported to NHSBT in December, after occurring in November (prior to the issue of continuous licences). This SAEAR was reported to the HTA three months later, after this was identified as a reportable SAEAR by a Regulation Manager in discussion with staff at NHSBT. The other four SAEARs reported outside of the next working day timeframe were all reported within three days. The other six SAEARs reported by NHSBT during Q4 were reported on time.

59. HTA staff attend regular meetings held by NHSBT to support implementation of the new requirements. At the last meeting a Regulation Manager discussed the reporting delays with NHSBT staff.

60. NHSBT may take a number of days to determine that an incident is an SAR / SAE and therefore reportable to the HTA. The HTA currently capture:

- the date that NHSBT are made aware of an incident; and
- the date that the report is created.

61. These dates are used to determine whether SAEARs are onwardly reported within one working day – as specified in the SLA with NHSBT. In most cases where NHSBT report outside the SLA time period, this reflects the time it takes NHSBT to consult with its organ advisory groups, to determine that the incident is actually an SAR or SAE.

62. To more accurately reflect NHSBT’s decision-making processes. The HTA will update its system to more accurately record the timing of reporting by changing “date NHSBT made aware” to “date NHSBT determine an incident as a SAEAR”.

Other regulatory activity
63. Paragraph 26 of this RAR refers to a regulatory alert issued after an RD Meeting resulted in the decision to suspend the import activity on a licence. The HTA issued a regulatory alert through the Regulatory Alert System for human Tissues and Cells (RATC). The RATC provides Competent Authorities of the European Union / European Economic Area (EU/EEA) and the European Commission with a network tool for the exchange of information on urgent measures to ensure the safety of human tissues and cells.

64. Pending further information from the German CA of its investigations of the US company, the HTA suspended the establishment’s import licence, with effect from 28 March 2013 and directed the company to recall all unused tissue products from end users. As the HTA cannot confirm which countries may have received tissues from the licensed establishment, it initiated an EU-wide recall. So far Competent Authorities in the Netherlands and Czech Republic have confirmed those countries are unaffected by the tissue recall. An update will be provided in Q1 2013 / 14.

65. At the request of the Minister of Justice in Northern Ireland (NI), the HTA is supporting HM Inspectorate of Constabulary (HMIC). As a result of the Association of Chief Police Officers (ACPO) recommendations on the management of tissue samples, the HMIC is leading a review of the Police Service in Northern Ireland (PSNI). The aim of the review is to:

- provide an independent assessment to the Minister of Justice on responses by all relevant agencies to the recommendations resulting from the ACPO audit; and
- to report findings to the NI Minister of Justice and the NI Policing Board in the summer.

66. The HTA will also provide advice to HMIC to inform meetings with PSNI, the Police Ombudsman and Criminal Justice Inspection Northern Ireland. The HTA will lead the inspection of the State Pathologist’s Department and Coroner’s Service and contribute to the drafting of the report.

67. One of ACPO’s recommendations was that review of police exhibits held on HTA licensed premises should be included within the regular HTA inspection process and that there should be a mechanism for reporting back to the police and the Home Office. This work with HMIC will inform how HTA takes forward this recommendation in the 2013 / 14 business year.
68. With the agreement of the Department of Health, the HTA is considering a request to conduct an inspection of mortuary facilities at a military hospital in Cyprus at the invitation of the Ministry of Defence (MoD). The role of the HTA will be non-statutory and advisory. All associated costs, including staff time, will be recovered and there will be no subsidy from either grant in aid or licence fee income. The work can be absorbed within existing resources without adversely affecting HTA business priorities. As the hospital is based on British Sovereign Territory, and the request has come from a government department, we have considered it appropriate to agree, in principle, to take on the project. We are currently discussing the scope of the project with the MoD. An update will be provided in Q1 2013 / 14.


69. The Q3 RAR stated the HTA will complete audits of all licensed establishments in ODT sector by the end of the 2013 calendar year. Five audits were completed by the end of Q4. Four single organ establishments and one multi-organ establishment were audited.

70. Common shortfalls have been identified around appropriate, written standard operating procedures and follow-up procedures for living donors. The team will issue some advice to the sector, through the e-newsletter, to provide an update to establishments which have not yet received their audit.

71. Further wider issues have been identified through the audit process, such as responsibility for using laboratories with Clinical Pathology Accreditation and responsibility for transport, which continue to be discussed internally and with NHSBT.

Action

72. Members are asked to note the content of this report.
Annex One

Sector-specific breakdowns of numbers of investigations, RD Meetings, non-routine inspections, legal notices issued and appeals heard, and HTARIs / SUIs in the previous six quarters.

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13 Q4</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q2</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>12/13 Q1</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q4</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q3</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Table 1: Numbers of investigations*

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13 Q4</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q3</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>12/13 Q1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q4</td>
<td>4*</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q3</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Table 2: Numbers of RAPs/Regulatory Decisions - the term, regulatory decision will be applied from Q3 (*two establishments were considered at one RAP)*

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13 Q4</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q2</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>12/13 Q1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q4</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q3</td>
<td>2</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

*Table 3: Numbers of non-routine inspections*
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

<table>
<thead>
<tr>
<th></th>
<th>Human Application</th>
<th>Post Mortem</th>
<th>Public Display</th>
<th>Research</th>
<th>Anatomy</th>
<th>ODT</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13 Q4</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12/13 Q2</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>12/13 Q1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q4</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>11/12 Q3</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Table 4: Numbers of legal notices issued
Accidental damage to a body \(^1\) & 6 & 10 & 5 & 4\(^+\) & 5 & 5  
Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination & 0 & 0 & 0 & 0 & 0 & 0  
Discovery of an organ or tissue following post-mortem examination and release of body & 1 & 0 & 0 & 0\(^+\) & 1 & 0  
Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family & 1 & 0 & 0 & 0 & 1 & 0  
Disposal or retention of a whole fetus or fetal tissue (gestational age less than 24 weeks) against the express wishes of the family \(^2\) & 1 & 0 & 0 & 0 & 0 & 0  
Disposal or retention of an organ against the express wishes of the family & 0 & 1 & 0 & 0 & 0 & 0  
Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services & 0 & 1 & 1 & 1 & 0 & 0  
Loss of an organ & 0 & 0 & 0 & 0 & 1 & 0  
Major equipment failure & 0 & 1 & 3 & 1 & 0 & 1  
Post-mortem examination conducted was not in line with the consent given or the Post-mortem examination proceeded with inadequate consent & 0 & 1 & 0 & 0 & 0 & 0  
Post-mortem examination of the wrong body & 0 & 0 & 0 & 0 & 0 & 1  
Release of the wrong body & 4 & 2 & 3 & 2 & 1 & 3  
Removal of tissue from a body without authorisation or consent & 0 & 0 & 0 & 0 & 0 & 0  
Serious security breach & 2 & 3\(^+\) & 1 & 1 & 1 & 0  
Viewing of the wrong body \(^2\) & 1 & 2 & 0 & 1 & 0 & 1  
Any other incident that could result in adverse publicity that may lead to damage in public confidence & 3 & 5 & 6 & 1 & 2 & 2  
**Total number of HTARIs in quarter** & **19** & **26\(^+\)** & 19 & 11 & 12 & 13

<table>
<thead>
<tr>
<th>Category</th>
<th>12/13 Q4</th>
<th>12/13 Q3</th>
<th>12/13 Q2</th>
<th>12/13 Q1</th>
<th>11/12 Q4</th>
<th>11/12 Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental damage to a body (^1)</td>
<td>6</td>
<td>10</td>
<td>5</td>
<td>4(^+)</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Discovery of an organ or tissue following post-mortem examination and release of body</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0(^+)</td>
<td>1</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>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</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 (^2)</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</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>0</td>
<td>0</td>
<td>0</td>
<td>0</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>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loss of an organ</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Major equipment failure</td>
<td>0</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Post-mortem examination conducted was not in line with the consent given or the Post-mortem examination proceeded with inadequate consent</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Post-mortem examination of the wrong body</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Release of the wrong body</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Removal of tissue from a body without authorisation or consent</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serious security breach</td>
<td>2</td>
<td>3(^+)</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Viewing of the wrong body (^2)</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Any other incident that could result in adverse publicity that may lead to damage in public confidence</td>
<td>3</td>
<td>5</td>
<td>6</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total number of HTARIs in quarter</strong></td>
<td><strong>19</strong></td>
<td><strong>26(^+)</strong></td>
<td><strong>19</strong></td>
<td><strong>11</strong></td>
<td><strong>12</strong></td>
<td><strong>13</strong></td>
</tr>
</tbody>
</table>

Table 5: Numbers of HTARIs in the PM sector reported to the HTA in the past six quarters. \(^1\) Category extended in December 2011 to include accidental damage to a body which was not scheduled for a PM examination. \(^2\) HTARI category introduced in December 2011. \(^+\) The following figures were adjusted following an annual review of all SUI / HTARI data for the 2012 / 13 business year.
<table>
<thead>
<tr>
<th></th>
<th>12/13 Q4</th>
<th>12/13 Q3</th>
<th>12/13 Q2</th>
<th>12/13 Q1</th>
<th>11/12 Q4</th>
<th>11/12 Q3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement</td>
<td>12</td>
<td>6</td>
<td>7</td>
<td>10</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Processing</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Testing</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Storage</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Distribution</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>End use</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Transportation</td>
<td>0</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Preservation</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Materials</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>6</td>
<td>7</td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Donor reaction</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Recipient reaction</td>
<td>3</td>
<td>2</td>
<td>9</td>
<td>2</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total number of SAEARs during that quarter</strong></td>
<td><strong>35</strong></td>
<td><strong>27</strong></td>
<td><strong>35</strong></td>
<td><strong>22</strong></td>
<td><strong>30</strong></td>
<td><strong>37</strong></td>
</tr>
</tbody>
</table>

*Table 6: Numbers of SAEARs in the human application sector reported to the HTA in the past six quarters.*
Living Donation Activity Report Q4

Purpose of paper

1. This report provides high level information on the activity of the Strategy and Quality Directorate in respect of its living donation responsibilities. This is referred to as the work of the Living Donation Assessment Team (LDAT) in order to differentiate from the other responsibilities of the Directorate which are reported elsewhere.

2. The team has responsibility for the systems which enable the consideration and approval of living organ donations; and the systems for considering and approving bone marrow donations from those who lack capacity or competence to consent to the donation.

Action

3. The Authority is asked to note the contents of the report and provide any comment.

Decision-making to date

4. SMT reviewed the content of the report and approved the paper for the Authority at its meeting in 2 May.

5. The Policy and Regulatory Activity Group (PRAG) reviewed the report at its meeting on 14 May.
General activity

6. The HTA has considered and approved 322 cases of living organ donation in Quarter Four (Q4). Additionally, the LDAT has considered and approved 25 bone marrow donation cases. Further detail on the types of cases is available on page 8.

7. Training was provided to one HTA staff member to provide additional support with directed donation cases.

Investigations and case review / decision meetings

Investigation One – Case T8122

8. Following submission of an Independent Assessor (IA) report we were advised that further information had come to light and the unit had postponed the surgery.

9. The donor had made a request for the surgery to be postponed for a couple of months. After further discussion with the donor, the unit had concerns with the donor’s psychological and financial wellbeing and decided they were not prepared to proceed with the donation for the time being.

10. The unit was advised that although the IA report was submitted, the case would not be considered by the HTA as the surgery was not being taken forward. We also assured them that the donor could be considered for donation in the future once the unit was satisfied that it was right for the donor to proceed.

Investigation Two - Case T7917

11. This case came to the HTA as a Directed Donation (Donor and Recipient have a pre-existing genetic or emotional relationship). The category was changed by the LDAT to a directed altruistic donation after it became clear that although the pair are cousins they had no emotional relationship before the need for a transplant arose.

12. It was clear that both the IA (who had attended enhanced IA training) and the unit had not recognised the case as a directed altruistic donation (DAD). The LDAT has provided further guidance and both now have improved awareness of the features of DAD cases.

13. The case was considered and approved by a panel.
Investigation Three – Case T7942
14. A case of a directed donation was referred to a panel as the IA could not establish clear evidence of an emotional relationship between the donor and recipient due to its complex nature. The case was considered as a directed altruistic donation but the panel could not be satisfied, based on the initial evidence provided by the IA, that there was no evidence of a reward.

15. The panel requested further evidence to be gathered through a series of questions prepared by a panel through an alternative IA.

16. Additional interviews were carried out with the donor and recipient with the objective of ascertaining the claimed relationship between donor and recipient and that there was no evidence of reward.

17. A further IA report was submitted and considered by the same panel and the case was approved.

Investigation Four – Case T7832
18. In December 2012, following a case review meeting a panel considered case T7832 and were not satisfied that there was no evidence of an offer of reward. The case was therefore not approved. An appeal was received and a Reconsideration Hearing was held in March 2013.

19. Following submission of witness statements and evidence provided in person by the donor, a fresh decision was made on the case by a new panel. The new panel approved the case.

20. A review of the case handling process and hearing process for this case will be carried out in May 2013 with a view to establishing lessons learnt and improvements that can be made in LDAT processes.

Novel cases

Novel Case One
21. A referral unit contacted the HTA with an adult to adult liver donation. The unit advised that an IA had been arranged at the transplant unit, however this required over an hour of travel for both donor and recipient. At that time the recipient was not fit to travel.

22. The unit was advised to proceed with the donor interview and to seek an interview with the recipient once they were well enough to be transferred. It was explained that an IA should attempt an interview with the recipient but if it was clear they lacked capacity to be interviewed the interview could be
halted and the IA would report on this basis in the report submitted to the HTA. When the recipient was well enough to be transferred an independent assessment was arranged but did not go ahead. Sadly the recipient passed away from complications.

**Enquiries**

**General enquiries**

23. We have seen an increase in the number of requests for information on Altruistic Donor Chains from IAs. It would appear that some units are not providing IAs with information on process changes. Guidance has been issued to Living Donor Coordinators (LDC) and IAs in the IA Bulletin on what the HTA requirements are when referring these types of cases.

24. We have also had an increase in enquiries about when the requirement for the donor and recipient to be interviewed together can be withdrawn. In particular, the enquiries have been for cases where the donor and recipient are not geographically close and it may be the donor’s preference to undergo surgery locally with the donated organ travelling to the recipient’s unit. This causes some difficulty when considering the HTA policy requirement for a donor and recipient to be interviewed both separately and together by the same IA.

25. This issue was presented to the Transplantation Working Group in February 2013 and will be taken to an Authority Meeting with policy recommendations. In the interim, guidance will be issued to Transplant Units (see Annex A).

26. Below are some examples of novel enquiries dealt with by the LDAT in Q4:

**Enquiry One**

27. A unit enquired whether a donor found through a matching website could be considered for living donation. Appropriate guidance was issued to the unit including the British Transplantation Society’s position statement on directed altruistic donation.

**Enquiry Two**

28. An enquiry was received from a HTA licensed private clinic regarding requirements for living liver donation. Advice was given on Living Organ Donation Framework and the unit was provided with the details of local IAs who could carry out the interviews with the potential donor and recipient.
**Enquiry Three**

29. An IA contacted the HTA after a recipient they had interviewed asked whether they could receive a copy of the IA report. The IA was advised that the recipient could request this directly from the HTA as a ‘Data Protection Act’ request. No request was received.

30. Subsequently the unit requested a copy of the report under the Freedom of Information Act. This was declined on the basis that it contained personal data about the donor and recipient.

**Legal Advice**

31. In January 2013 advice was sought from counsel on the sufficiency of evidence the HTA relies upon when considering a living donation case and the wider issues of evidence on duress, coercion and reward.

32. The HTA received case specific advice, and will be provided with general advice on this issue. Once the final advice is received, relevant guidance will be issued and training provided to HTA staff and Authority Members where necessary.

**Engagement with Independent Assessor and Accredited Assessor communities**

**IA Bulletins**

33. One IA Bulletin was issued in Q4 which addressed a number of issues including: the process for referring donors and recipients for altruistic donor chains, identifying the medical practitioner for the donor, the IA survey, revisions to HTA Code of Practice 2, distinguishing directed donation from directed altruistic donation cases and the use of interpreters during IA interviews.

**Accredited Assessor (AA) training request for bone marrow donations**

34. A request was received from a unit in Birmingham for training to be delivered to new AAs. The unit is finding it increasingly difficult to arrange AA interviews and would like more of their staff trained as AAs. This request is being considered by the LDAT.
Working with stakeholders

Collaborative working on UK guidance on donors / recipients in prison
35. A representative from the LDAT has been invited to attend a meeting between various organisations including the Department of Health and NHS Blood and Transplant in order to agree and draft guidance for Transplant Units on handling donors / recipients who are in prison.

HTA Transplant Advisory Group (TAG)
36. A number of policy areas were considered at the meeting of the Transplantation Working Group (TWG) in February 2013. Recommendations will be presented to forthcoming meetings of the Authority for discussion and approval.

37. It was agreed that as of 2013/14 the Group would be referred to as the ‘Transplant Advisory Group’ in recognition of the Group’s remit.

Review of 2012/13 living donation activity
38. As can be seen on page 8, we have seen a significant increase in Non-Directed Altruistic kidney donation cases over the past year, 65 more cases than in 2011/12 (an increase of 171%). We have also approved our first case of Non-Directed Altruistic liver donation.

39. We will continue to see growth in non-directed altruistic donations, particularly as units become more used to offering the option of triggering a chain of donations. This is anticipated to be a popular option for Non-Directed Altruistic donors because their donation will have a greater impact as more people will receive a transplant as part of a chain.

40. In total (for 2012/13) 1,243 cases were considered by the HTA (97% of these were for kidney donation). This equates to an increase of 2.1% on cases considered by the Executive and Authority Members on the previous business year (1,217 cases in 2011/12).

Action
41. Members are asked to note the content of this report.
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

Living organ donation cases approved in Q4 2012/13

<table>
<thead>
<tr>
<th>Type of case</th>
<th>TOTALS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of cases approved</td>
</tr>
<tr>
<td>Directed kidney</td>
<td></td>
</tr>
<tr>
<td>Directed altruistic kidney</td>
<td></td>
</tr>
<tr>
<td>Non-directed altruistic kidney</td>
<td></td>
</tr>
<tr>
<td>Non-directed altruistic liver</td>
<td></td>
</tr>
<tr>
<td>Paired or pooled kidney</td>
<td></td>
</tr>
<tr>
<td>Directed liver lobe</td>
<td></td>
</tr>
<tr>
<td>January</td>
<td>90</td>
</tr>
<tr>
<td>February</td>
<td>96</td>
</tr>
<tr>
<td>March</td>
<td>73</td>
</tr>
<tr>
<td>Total Q4</td>
<td>259</td>
</tr>
<tr>
<td>Total Q3</td>
<td>266</td>
</tr>
<tr>
<td>Total Q2</td>
<td>244</td>
</tr>
<tr>
<td>Total Q1</td>
<td>271</td>
</tr>
</tbody>
</table>

Bone marrow cases approved in Q4 2012/13

<table>
<thead>
<tr>
<th>Bone Marrow / Peripheral Blood Stem Cells</th>
<th>Approvals by the Living Donation Assessment Team</th>
</tr>
</thead>
<tbody>
<tr>
<td>January</td>
<td>8</td>
</tr>
<tr>
<td>February</td>
<td>9</td>
</tr>
</tbody>
</table>
HTA meeting papers are not policy documents. Draft policies may be subject to revision following the Authority meeting.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>March</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>Q4</td>
</tr>
<tr>
<td>Total</td>
<td>Q3</td>
</tr>
<tr>
<td>Total</td>
<td>Q2</td>
</tr>
<tr>
<td>Total</td>
<td>Q1</td>
</tr>
</tbody>
</table>
Annex A

Holding position on the use of video conferencing / Skype for independent assessment interviews:

The HTA has received a number of enquiries about whether we allow donor and/or recipient interviews to take place remotely using developing technologies, such as Skype.

At the current time, the HTA will not grant approval for a remote interview as a matter of course. This is a result of a number of issues associated with interviews undertaken in this manner and the potential consequences for the HTA in discharging its statutory responsibilities effectively. Among these issues are:

- The level of regulatory risk associated with the case – for example, directed altruistic donation cases require a higher degree of scrutiny which may be harder to achieve remotely.
- The need to be assured that the person being interviewed is who they claim to be.
- The need to ensure that the donor is being interviewed in a controlled environment where he or she cannot be placed under duress during the course of the interview.
- The logistics of the joint donor and recipient interview, and the possible reduction in the IA’s ability to assess the dynamics of the donor and recipient relationship.
- The logistics of involving an interpreter where this is necessary.

Although remote interviews may be more convenient for participants under certain circumstances, we believe that the need for reliable regulation should not be a victim of this convenience.

The HTA is in the process of developing a policy on whether, and under what circumstances, to allow remote interviewing. In the interim, where you believe exceptional circumstances make remote interviewing necessary, the full circumstances of the case should be submitted to the HTA who will decide whether or not to approve the request on a case-by-case basis.
Communications Evaluation Report Q4

Purpose of paper

1. This report forms the evaluation strand of the HTA’s communications strategy. Its purpose is to provide regular and consistent performance metrics on the HTA’s communications activity, specifically media, digital communications, stakeholder engagement and enquiries.

2. This report evaluates communications activity from 1 January 2013 – 31 March 2013 (Q4).

Action

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

Decision making process to date

4. The Communications Advisory Group (CAG), previously the Communications Members’ Group, met in February 2013 to provide comment about the style of the new report. These comments have been incorporated in this paper.

5. SMT reviewed the content of the report and approved the paper for the Authority at its meeting in 2 May.
Media activity

HTA mentions

6. The HTA focuses on qualitative evaluation of media coverage. We judge its tone (positive, neutral or negative) as well as counting the number of mentions in national, regional, broadcast, trade and online press.

7. In Q4 we had 21 HTA mentions in a wide variety of local, trade, national and online media (all reported in the weekly HTA News Digest). This was a slight increase from the 18 mentions in Q3. The table below shows the tone of coverage for Q4 compared with Q3.

<table>
<thead>
<tr>
<th>Tone of coverage</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>7</td>
<td>10</td>
</tr>
<tr>
<td>Neutral</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>21</td>
</tr>
</tbody>
</table>

7. Coverage in Q4 was 86% positive / neutral. This compares with 96% in Q3. This is measured against our 2013 / 14 objective of 90% positive / neutral.

8. Of the three negative stories, one was concerned with the process of non-directed altruistic donation, and two implied that regulation (in general) holding back scientific research.

9. We also divide the coverage into subject / sector. The table below shows the subject type for Q4 compared with Q3.

<table>
<thead>
<tr>
<th>Subject type</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>Organ donation</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Research</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Body Donation/Anatomy</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Post mortem</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Human application</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
10. The ‘corporate’ figure is higher this quarter primarily because of the coverage following the ALB review decision in January.

**HTA proactive stories / biggest stories**

11. In Q4, we published 12 stories on our news webpage (not all were issued as media releases to journalists), including:

- The HTA response to the Government announcement on our future. HTA Chair, Baroness Diana Warwick, welcomed the Government’s decision and said that an independent review would be an opportunity to build on our positive reputation. She also thanked the HTA’s stakeholders for their support. The ALB decision was reported widely, including in the *Guardian, Independent, Nature*, the *Health Service Journal, Research Fortnight, BioNews* and *MSN online*.

- A media statement in response to a BBC story relating to tissue retained by the police.

- The announcement of a perinatal post mortem package, developed by Sands, the stillbirth and neonatal death charity, in consultation with the HTA. This was published in a feature in the *Independent*. The HTA provided a quotation on Sands’ launch news release.

- Other stories included: the revised Code of Practice for organ donations; the government consultation on implementing reforms to the coroner system; changes to post-mortem incident reporting and the storage of microscope slides; and a new position statement on storage of human material for teaching by schools and colleges.

12. The communications team also produced briefings and lines to take in preparation for potential media interest that may have an impact on public confidence or our reputation.

**Media enquiries**

13. In Q4, we had 22 media enquiries, compared with 28 in Q3. Most of these were for background advice and questions, especially on our role in relation to living organ donations and in public display. The table below shows the type of enquiries for Q4 compared with Q3.

<table>
<thead>
<tr>
<th>Legislation/Regulations</th>
<th>0</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>18</td>
<td>21</td>
</tr>
</tbody>
</table>
14. Our objective in 2013/14 is that 100% of media enquiries are responded to within the journalist’s deadline. In Q4, as in the Q3, the response rate was 100%.

**Stakeholder / public and patient engagement**

15. Alan Clamp, Diana Warwick, Shaun Griffin, and / or other members of SMT have been involved in numerous meetings in this three month period, including with:
   - Felicity Harvey, Director General for Public Health,
   - Anna Soubry MP, Minister for Public Health,
   - Justin McCracken, HPA Chief Executive,
   - Peter Thompson, HFEA Chief Executive,
   - Lisa Jardine, HFEA Chair,
   - Rachel Bosworth, MHRA Director of Communications (with the MHRA, HTA and HRA communications teams), and
   - Quarterly meeting with DH colleagues

16. Alan and some SMT members also attended the:
   - CQC event on their strategy review, and the
   - British Transplantation Society conference.

**ALB consultation**

17. The Government’s response to the ALB consultation was published in January 2013. The Government also published all of the responses that it had received from stakeholders.
18. Of the 109 responses, 55 were about the HTA, 35 about the HFEA, and 19 about both organisations.

19. Of the 74 that related to the HTA:
   - 63 were positive about the HTA and / or in favour of option 3
   - 7 supported the transfer of functions
   - 4 offered no real opinion.

20. This equated to over 90% of responses being either positive or neutral about the HTA and its work.

21. The consultation responses that supported the transfer of functions focused on arguments around cost effectiveness and efficiency, the number of regulators in this area, concerns about the complexity of regulatory landscape, and confusion and overlap between regulators.

22. Baroness Warwick wrote to the 50 organisations that responded to the ALB consultation positively about the HTA (the other 13 positive responses were from individuals for whom contact details were not published). In the letter, Diana thanked stakeholders for their support and outlined some of the ways the HTA is becoming even more efficient and effective, following many suggestions offered by stakeholders in their responses.

Public engagement

23. The HTA and Professional Standards Authority (formerly the Council for Healthcare Regulatory Excellence) held two joint seminars discussing issues around consent (in December 2012 and March 2013). The first event was with members of the public and organisations representing patients (as reported in Q3); the second was with professional bodies overseen by the Professional Standards Authority (such as the General Medical Council), regulators with an interest in consent, and representatives from the December event.

24. Both events focused on case studies around post-mortem examination and cord blood collection. They covered qualifying relationships and disputes which may arise within a family, information provided to a family about the procedures for which consent is being sought, the roles of professionals in the consent process, and the training required. In addition, there was a discussion around the terminology of consent. Feedback from both events was 100% positive.

25. A report of the meeting, presentations from the events and recommendations will be available on our website soon, and will inform future advice and guidance.
Parliamentary engagement

26. On 16 January, Baroness Warwick took part in a short debate in the House of Lords on medical innovation, initiated by Lord Saatchi, as background to the Medical Innovation Private Members Bill. Diana said that regulation need not stifle innovation and that it provided assurance for quality and safety. She added that the HTA believes that a key role of a regulator is to provide clarity, and to support organisations in working through the quality and safety regulations.

27. On 8 January, Alan Clamp gave evidence to the House of Lords Science and Technology Committee as part of its inquiry into the future of regenerative medicine. In his evidence, which he gave alongside chief executives of other regulators in this area, he highlighted the importance of regenerative medicine and research, and emphasised the HTA’s aim to ensure that high quality translational research thrives in the UK. Alan also discussed HTA collaboration with other regulators and the important role regulation plays in supporting this rapidly developing field, providing essential safeguards for ensuring quality and safety, and that EU standards are met.

28. Following this evidence session, the HTA took the lead in pulling together a piece of joint evidence with the HFEA, HRA and MHRA. This was submitted to the Committee at the end of March. The document clarifies some of the questions asked at the evidence session by further explaining the roles of the different regulators in regenerative medicine, how the legislation aligns, and how we work to reduce regulatory burden on researchers through collaboration and other initiatives. We will also publish the document on our websites and, we hope, alongside the DH stem cell tool kit in due course. We expect the Committee’s report to be published in May or June.

29. The HTA submitted written evidence to the Joint Committee on the Draft Care and Support Bill. This Bill contained clauses that would abolish the HTA and the HFEA. Our submission focused on the risks associated with abolishing the HTA and transferring its functions elsewhere, and the benefits of retaining the HTA as a specialist regulator. Following the Government’s announcement about the future of the HTA, it was recommended that these clauses be removed from the Bill. Section 10 of the final report contained a number of quotes from organisations speaking positively about the HTA.

Welsh Health and Social Care Committee

30. Alan Clamp gave evidence on 30 January to the Health and Social Care Committee of the Welsh Assembly on the Human Transplantation (Wales) Bill.
Alan’s contribution followed the written evidence submitted to the Committee in Q3 and Q4.

**HTA, CQC, HFEA Memorandum of Understanding and Joint Working Protocol**

31. In January the HTA published new Memorandums of Understanding and Joint Working Protocols with the Care Quality Commission (CQC) and HFEA. These will permit the sharing of information about organisations that are registered or licensed by more than one of these regulators.

**Substances of Human Origin: Vigilance and Surveillance Project**

32. In February, the HTA hosted the final meeting of the recently-completed three-year Substances of Human Origin: Vigilance and Surveillance Project, co-funded by the European Commission Public Health Programme. As a project partner, the HTA hosted the final meeting in London. The Communications Team supported Regulation Directorate with the publication and launch of the SOHO V&S Guidance for Competent Authorities. The final report for the project can be downloaded from the SOHO V&S project website.

**HTA e-newsletter**

33. The January and March editions of the HTA’s external e-newsletter were sent out to nearly 9000 subscribers.

34. The January issue contained the results of a snapshot survey to find out readers’ views about our e-newsletter. Eighty six readers responded. The survey found that:
   - The HTML version of the e-newsletter was most popular with 63% of respondents using this format;
   - 74% of respondents felt the bi-monthly frequency of the e-newsletter was adequate and 87% felt the length of articles was about right;
   - 96% preferred to read it via email, as opposed to 5% who wanted to read it via the website;
   - 61% of respondents heard about the e-newsletter via the website. 40% heard via colleagues, demonstrating the effectiveness of peer recommendations in generating subscriptions.

35. The survey highlighted positive feedback about the content of the newsletter and over the coming months we will improve the look and accessibility of the newsletter by creating a new newsletter template which will allow us more flexibility. We will also drive more readers to longer articles on the HTA website, and make better use of links in the newsletter to increase accessibility.
36. More results from the survey and quotes from respondents are on the HTA website. The survey will be repeated in November 2013.

**Enquiries**

37. During Q4 we recorded 735 enquiries, compared to 844 in Q3. This includes:
- 476 enquiries from members of the public, of which 419 were about body donation (a reduction from 573 in Q3) and 57 general enquiries
- 259 enquiries from professionals (a small increase from the 216 enquiries recorded last quarter), the majority of the increase was attributable to licensing enquiries. The other enquiries from professionals tended to reflect the broad remit of the areas we regulate
- 22 enquiries from the media (as reported in Para 13).

38. The table below shows the type of enquiries for Q4 compared with Q3.

<table>
<thead>
<tr>
<th>Enquiry type</th>
<th>Q3</th>
<th>Q4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body donation</td>
<td>573</td>
<td>424</td>
</tr>
<tr>
<td>Tissue and cells for patient treatment</td>
<td>32</td>
<td>29</td>
</tr>
<tr>
<td>Licensing</td>
<td>43</td>
<td>63</td>
</tr>
<tr>
<td>Research</td>
<td>28</td>
<td>22</td>
</tr>
<tr>
<td>Post mortem</td>
<td>26</td>
<td>32</td>
</tr>
<tr>
<td>Other</td>
<td>112</td>
<td>113</td>
</tr>
<tr>
<td>FOIs</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Parliamentary questions</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Media enquiries</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>Total</td>
<td>844</td>
<td>735</td>
</tr>
</tbody>
</table>

39. From April 2013 we will record the numbers of information packs issued to members of the public about body donation.

40. As reported in Q3, we are looking into improving the way enquiries are recorded to make the categories clearer and give us better data.

41. The HTA’s KPI is for 95% of enquiries to be answered in ten working days. 91% were answered within this target in Q4 (compared with 89% in Q3). When Freedom of Information (FOI) requests are removed – which are answered
within 20 working days – the figure rises to rises to 93% in Q4, compared with 90% in Q3.

42. During this period, we had 10 Freedom of Information (FOI) requests, compared with 10 in the previous quarter. All of the requests were responded to within the 20 day statutory time limit. Where the material is new and of wider interest, we publish FOI disclosures on our website.

43. The FOI requests concerned incidents reported to the HTA, suppliers of goods and services to the HTA and the content of an Independent Assessor’s report.

44. We received 14 parliamentary questions (PQs) in Q4, this compares with none in Q3. The 14 PQs included eight questions from Priti Patel MP (Witham) on redundancy, retirement, sickness, allowances and bonuses, one from Chi Onwurah MP (Newcastle Upon Tyne Central) on the cost of overtime, and five from Lord Phil Willis of Knaresborough on salaries and total cost of finance, communications and administration departments in ALBs. Ten of the PQs were directed to the DH and all its non-departmental public bodies. The remaining four (from Lord Willis) were directed to the HTA, HFEA, HRA and MHRA.

**Digital communications**

**Website**

45. The HTA introduced cookies with Google Analytics on 12 October 2012. Google Analytics is widely used, and offers a better understanding of behaviour and demographics of website audience. This is the first full reporting period for which we have had Google Analytics. In the next report we will be able to compare Q3 2012/13 with Q1 of 2013/14.

46. Google Analytics shows that there were approximately 69,000 visits to the HTA website and 52,000 unique visitors in Q4. Web Trends – the program we previously used to measure web visitors – shows that there were 188,000 visits and 108,000 unique visitors in Q4. This does not mean that there has been a reduction in the number of visitors to the website. If the Webtrends statistics are compared with the equivalent period last year, the figures are similar.

47. However, the numbers reported by Google Analytics are significantly lower than those reported by Webtrends. Whilst Webtrends counts every visit to the website, Google Analytics excludes certain types of visitors, for example ‘non-human’ searches (searching ‘spiders’ for example account for 17,000 of the visits counted by Webtrends). We therefore consider Google Analytics be more accurate for our purposes.
48. Google Analytics shows that most visitors (79%) came from the UK, 7% came from the USA and 73% are new visitors. Visitors stay on the website for an average of 2 minutes 45 seconds, and visit approximately three pages per visit.

49. The NHS (.nhs email address) continues to be the highest single service provider visiting our website. People visiting from .nhs addresses stayed on the website longer (3 minutes and 50 seconds), visited more pages (5 pages per visit), and 50% of them were new visitors. The longer time and increased number of pages visited by those .nhs addresses is in line with the expected audience for the website.

50. The table below shows the percentage of website traffic for Q4 compared with Q3.

<table>
<thead>
<tr>
<th>Traffic</th>
<th>Q3 %</th>
<th>Q4 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Search traffic</td>
<td>70</td>
<td>69</td>
</tr>
<tr>
<td>Referral traffic</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Direct traffic</td>
<td>17</td>
<td>18</td>
</tr>
</tbody>
</table>

51. Traffic referred to us from other websites also stays on our website longer and more pages are viewed per visit than those coming from search engines or directly.

52. Following the release of the e-newsletters, there were small peaks of page views on the e-newsletter webpage.

53. By far the most popular pages on the HTA website are those on body donation, which received approximately 39,500 page visits in Q4. This equates to 19% of all page visits (there were 212,000 page visits in Q4). Given the number of enquiries we receive on this subject from the public, we can infer that the vast majority of people looking at this page are members of the public (however, the web statistics do not provide this information). Other popular pages are the codes of practice and information about legislation.

Social media

54. The HTA’s Twitter account has 272 followers, up from 233 in Q3, we have 248 Facebook ‘likes’, up from 233 in Q3. This represents a 17% and 6% increase on Twitter and Facebook, respectively.
55. We have continued to cross-promote our different digital channels through the front page of our website, e-newsletter, and a wider presence on social media (see below). There were 339 visits to the website referred directly from social media channels, mainly from Twitter, this has increased from 262 last quarter.

56. Twitter followers include the All Party Parliamentary Group on Breast Cancer, the Welsh Government and their Health Minister, Royal Colleges of Pathologists and Surgeons, Medical Research Council, the Academy of Medical Sciences, a number of patient groups, members of the public, and several national health correspondents.

57. In this period we introduced an HTA LinkedIn channel as part of the digital strategy, which now has 70 followers – about 50% of them are existing staff or former colleagues.

Future activities

58. We recently approved Ipsos MORI to undertake the 2013 HTA public and professional survey. The survey will cover public and professional confidence in the regulation of human tissue, and professional advocacy (Key Performance Indicator). The professional survey will take place in June / July, with the public one taking place in August.

59. The title of the Annual Review of the Year event will be *Regulation: in the public interest?* We have secured Stephen Dorrell MP, Chair of the Health Select Committee, Peter Walsh, Chief Executive of Action against Medical Accidents and Richard Woodfield, Group Manager at MHRA as speakers. We are also in the process of gathering information for the 2013 Annual Review of the Year publication.

60. We are planning a second Parliamentary event in October.

61. We will provide the Authority with further information about all of these activities in the coming months.
Authority Paper

Date 28 May 2013  Paper reference HTA (32/13)
Agenda item 15  Author Sue Gallone

Authority scrutiny of risk register

Purpose of paper
1. This paper presents the latest strategic risk register.

Action
2. Members are invited to review the strategic risk register (Annex A).

Decision-making process to date
3. This paper is for information and the contents have not required any decisions to be made. SMT have reviewed the risk register and are content.

Background
4. Members are provided with a monthly update of the strategic risk register, to assure themselves that risks are being managed properly. The update consists of the risk register with changes annotated and a log of changes.

5. The Audit Committee also review risk management in more detail at their meetings three times per year.

Risk register
6. The Senior Management Team (SMT) last reviewed the risk register on 2 May 2013. There were minimal changes, which are shown in tracked changes, and a log of changes is attached at Annex B. SMT confirmed that the actions the HTA can take to manage risks are in hand.
7. The risk of failure to manage change is our highest risk at present, because of uncertainty the HTA still faces, and is amber. The other amber risk is inability to deliver our statutory remit, primarily due to turnover of staff.

8. SMT are content that the strategic risk register is complete and accept the level of risk identified.

Annex A – Strategic risk register, May update
Annex B – Log of changes to strategic risk register
HTA Strategic Risk Register
May 2013

Overview:
No significant changes. Failure to manage change and deliver our statutory remit continue to be the key strategic risks.

Other notable risks:
The introduction of draft legislation in Wales has implications for how the HTA works in Wales, and possibly in the UK. The HTA is managing the changes associated with the new legislation.
The independent review of the HTA (and HFEA) is causing uncertainty about future structure.

<table>
<thead>
<tr>
<th>Risk</th>
<th>January 2013</th>
<th>February 2013</th>
<th>March 2013</th>
<th>April 2013</th>
<th>May 2013</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Statutory remit</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Risk remains amber due to the demands on experienced staff to deliver routine business and process improvements. Recruitment and development of staff is underway to help this become green, and more stability (less turnover) is required too. This will take some time (there are three staff on maternity leave) and there is still anxiety about pay and the future.</td>
</tr>
<tr>
<td>2 – Managing change</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>The HTA continues to live with uncertainty, pending the outcome of the independent review of the HTA and HFEA. The potential proximity of the decision, and change likely due to the Welsh legislation, means that the risk remains amber.</td>
</tr>
<tr>
<td>3 – Major event</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This risk could have a high impact but processes are in place to manage it.</td>
</tr>
<tr>
<td>4 – Financial resources</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>This risk is low at present and the reduction of reserves has been managed.</td>
</tr>
<tr>
<td>5 – Relationship management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Relationships remain good and there is evidence of confidence in the HTA in feedback. We are alert to the potential impact of the independent review and possible responses to the HTA on the draft Code of Practice following the Welsh legislation.</td>
</tr>
</tbody>
</table>

Risks are assessed by using the grid below:

- Impact
  - Catastrophic
  - Significant
  - Moderate
  - Minor
  - None

- Likelihood
  - 1. Rare
  - 2. Unlikely
  - 3. Possible
  - 4. Likely
  - 5. Almost Certain
  - Almost定

Formatted Table
<table>
<thead>
<tr>
<th>Ref</th>
<th>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>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sarah Bedwell</td>
<td>Inability to carry out its statutory remit (strategic objective 1)</td>
<td>I</td>
<td>L</td>
<td></td>
<td>Ongoing</td>
<td>4</td>
<td>Strategic plan and business plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, pay levels, inadequate contingency planning and the uncertainty around the HTA/HFEA review.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insufficient capacity due to difficulty in recruiting and retaining Independent Assessors (IAs)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inadequate business planning as existing resources not used in most cost effective manner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional simultaneous work pressures and insufficient focus on operational and change management circumstances</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Closer of practice not in line with legislation and not subject to independent review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uncertainties about future and transition</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Uncertainty about reappointment of Authority members in 2014</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Key system failure (e.g. CRM)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effects of inability to inspect all sectors in line with business plan objectives</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ability to deliver sufficient advice and guidance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inadequate business planning in HTA sector</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reduced confidence in staff from regulated sectors &amp; increased likelihood of challenge to decisions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fewer Members increases pressure on others to consider transplant cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Leading to:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Loss of public confidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Judicial review</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reputational damage</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intervention by sponsor body</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Additional costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Inability to carry out its statutory remit (strategic objective 1) - Risk Owner: Sarah Bedwell

- Insufficient capacity and/or capability, including insufficient expertise, due to staff attrition, pay levels, inadequate contingency planning and the uncertainty around the HTA/HFEA review.
- Insufficient capacity due to difficulty in recruiting and retaining Independent Assessors (IAs).
- Inadequate business planning as existing resources not used in most cost effective manner.
- Additional simultaneous work pressures and insufficient focus on operational and change management circumstances.
- Closer of practice not in line with legislation and not subject to independent review.
- Uncertainties about future and transition.
- Uncertainty about reappointment of Authority members in 2014.
- Key system failure (e.g. CRM).

**Effects:**
- Inability to inspect all sectors in line with business plan objectives.
- Ability to deliver sufficient advice and guidance.
- Inadequate business planning in HTA sector.
- Reduced confidence in staff from regulated sectors & increased likelihood of challenge to decisions.
- Fewer Members increases pressure on others to consider transplant cases.

Leading to:
- Loss of public confidence.
- Judicial review.
- Reputational damage.
- Intervention by sponsor body.
- Additional costs.

**Actions to improve mitigation:**
- Strategic plan and business plan.
- Ongoing review of performance and priorities.
- Quarterly accountability meetings with DH.
- Resource and efficiency plans.
- Training and development of professional competence.
- Communications about review.
- CRM development and support contract.
- Business continuity plan.
- Staff benefits in place.

**Source of Assurance:**
- Monthly reports to BPRG.
- Matters raised by Directors at SMT – SMT minutes.
- Minutes of DH quarterly review meetings.
- Monthly strategic performance reviews to Authority.
- Monthly finance reports to Authority.
- Staff forum minutes.

**Assured position:**
- Same.

**Comment:**
- Contingency plans would focus strictly on legislative requirements.
<table>
<thead>
<tr>
<th>Ref</th>
<th>Risk 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>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Failure to manage change (underpins delivery of all strategic objectives and directly impacts on 3, 4 and 5)</td>
<td>4 3</td>
<td>Ongoing</td>
<td>• Corporate leadership by SMT and Heads&lt;br&gt;• Change activity reflected in business plan with appropriate prioritisation&lt;br&gt;• Succession planning – staff development ( eg Hub, CIS)&lt;br&gt;• Resource and efficiency plans in place&lt;br&gt;• Contributing to BSST programme&lt;br&gt;• Networking with other ALBs and seeking to work collaboratively with HFEA and CiC and others&lt;br&gt;• Internal communications strategy and mechanisms for communicating in place&lt;br&gt;• Engage key domestic and European stakeholders&lt;br&gt;• MoU signed with CiC and HFEA re collaborative working</td>
<td>4 3</td>
<td>• Support DH and work with stakeholders in responding to any recommendations arising from the independent review (AC lead)&lt;br&gt;• Discuss HTA plans with BSST programme (SGa) as required&lt;br&gt;• Collaborative working with CiC, HFEA, MHRA, NHSLA, CPA and HRA (AC lead) Ongoing&lt;br&gt;• Engagement and communication with staff (AC lead) Ongoing&lt;br&gt;• Active engagement with Wales (AMS lead) Ongoing</td>
<td>• SMF minutes record change discussions and actions&lt;br&gt;• Transition risks log&lt;br&gt;• Memoranda of understanding&lt;br&gt;• Major change initiatives reports to Authority meetings every 2 months</td>
<td>Same</td>
<td></td>
</tr>
<tr>
<td>Ref</td>
<td>Risk</td>
<td>Risk Owner</td>
<td>Cause and Effects</td>
<td>Inherent Risk Priority</td>
<td>Proximity</td>
<td>Existing Controls/Mitigations</td>
<td>Residual Risk Priority</td>
<td>Actions to improve mitigation</td>
<td>Source of Assurance</td>
</tr>
<tr>
<td>-----</td>
<td>------</td>
<td>------------</td>
<td>------------------</td>
<td>-----------------------</td>
<td>----------</td>
<td>----------------------------</td>
<td>-----------------------</td>
<td>--------------------------</td>
<td>----------------------</td>
</tr>
</tbody>
</table>
| 3   | Inability to manage an actual or potential major event, such as retention of tissue or serious injury or death to a person resulting from a treatment involving processes regulated by the HTA (underpins delivery of all strategic objectives) | Alan Clamp | - Insufficient capacity and/or capability  
- Multiple major events  
- Lack of leadership  
- Lack of clear regulatory processes to ensure compliance with standards  
- Acting in an unlawful manner  
- Failure to work effectively with partners/other organisations  
- Inability to contact SMT/Senior staff/Chair | S | Future, should event occur | Filled identified business-critical roles  
- Resource plan in place  
- Crisis management policy and guidance in place and communicated to staff  
- Media handling policy and guidance in place to supplement media release and enquiries SOPs  
- Crisis communications plan regularly reviewed  
- Annual crisis training  
- Business continuity plan regularly reviewed and tested  
- Accessible lines to take and key messages for likely scenarios  
- Media training for key staff & members with relevant scenarios  
- Media awareness for staff  
- SMT/Heads/Comms trained on major event communications  
- Comms team have staff and key Board contacts for media issues  
- Take legal advice  
- Agreed chain of approval to mitigate against staff/Chair absence  
- Mutual support from HFEA, CQC to support risk awareness  
- Fit for purpose Police Referrals Policy  
- Refresher regulation training programme in place  
- Decision-making framework and onward delegation scheme agreed by the Authority  
- Crisis related SOPs in place | 2 | Awareness raising on decision making at all staff meetings (AMS)  
May 2013  
- Report on quality assurance and agree priority actions for 2013/14 with Authority (JS/AMS)  
July 2013 | Internal audit report  
Regulatory Activity Report  
Living Donation Activity Report  
Communications Evaluation report | Same | Monthly reports to HTAMG  
- Matters raised by Directors by email or at SMT – SMT minutes  
- Minutes of DH quarterly review meetings  
- Monthly strategic performance reviews to Authority  
- Internal audit report  
- Regulatory Activity Report  
- Living Donation Activity Report  
- Communications Evaluation report |
<table>
<thead>
<tr>
<th>Ref</th>
<th>Risk</th>
<th>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>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
</table>
| 4   | Insufficient financial resources (underpins delivery of all strategic objectives and directly impacts on 5) | Sue Gallone | Cause  
- Fee payers unable to pay  
- Licence fee structure doesn't bring in sufficient fee income  
- Establishments change leading to less fee income  
- Reduction in Grant-in-aid  
- Increases in regulatory responsibilities – ‘do more with less’  
- Poor budget and/or cash-flow management  
- Reduction in reserves by end 2012/13  

Effect  
- Payments delayed  
- Reduction in staff and other expenditure  
- Increased licence fees  
- Request for further public funding  

Leading to:  
- Inability to deliver operations and carry out statutory remit  
- Reputational damage | 4 4 | 2012/13 at earliest | 3 1 | Budget management framework to control and review spend and take early action  
- Financial projections  
- Cash flow forecasting and monitoring  
- Licence fee modeling  
- Rigorous debt recovery procedures  
- Reserves policy and levels of reserves  
- Delegation letters set out responsibilities  
- Reserves policy | Monthly finance reports to Authority  
- Annual external audit  
- Audit Committee | Same |
<table>
<thead>
<tr>
<th>Ref</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>Source of Assurance</th>
<th>Assured position</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Inadequate relationship/stakeholder management (strategic objective 2)</td>
<td>Risk Owner: Shaun Griffin</td>
<td>4 4 Ongoing</td>
<td>Effective engagement with stakeholders on key regulatory issues</td>
<td>3 2</td>
<td>Ensure HTA’s expectations on Governance arrangements are made clear in our discussions regarding the future</td>
<td>Communications evaluation reports to Authority and Communications Advisory Group, meetings quarterly and meeting minutes</td>
<td>Same</td>
<td>Deleted: “Regular communications with transplant community”</td>
</tr>
</tbody>
</table>

- Inadequate relationship/stakeholder management (strategic objective 2)
  - Insufficient capacity/capability to communicate
  - Lack of engagement of Authority members and staff in communications
  - Inconsistent communication
  - Ineffective knowledge management
  - Inconsistencies in regulatory enforcement
  - Failure to explain our regulatory action and rationale for decisions
  - Failure to engage professional bodies and Government departments
  - Perception of insufficient professional expertise on Board and in support of Executive
  - Impact of organ donation proposals in Wales
  - Ineffective regulatory processes
  - Failure to act in a timely manner
  - Joint working with other organisations (may impact adversely on HTA approach)

- Effect
  - Complaints to HTA and/or government
  - Poor regulatory compliance
  - Reputational damage
  - Reduction in public and professional confidence

- Risk Owner: Shaun Griffin

- Effective engagement with stakeholders on key regulatory issues
- Ongoing engagement with Department of Health, OGDs, NDPBs and devolved administrations
- Communications and media strategies and mechanisms for implementing (e-newsletter, website etc) and staffing in place
- Media training for SMT and Members
- Strong HTA brand and identity
- Authority has position on deemed consent for organ donation
- HTA represented in advisory capacity on Welsh organ donation expert reference group
- Post-ALB review Communication plan

- Ensure clarity of purpose and benefits of collaborative working communicated (SB) Ongoing
- Survey of opinion of public and professions (SGr) Summer 2013, results in September
- Key stakeholder maps and agreed engagement plan revised for 2013/14 (SGr) May 2013

- Feedback from and minutes from Histopathology Working Group and Transplant Working Group
- Feedback from surveys (stakeholder evaluation completed every 3 years and ad hoc surveys)
Log of changes to Strategic Risk Register – May 2013

<table>
<thead>
<tr>
<th>Risk</th>
<th>Column</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front sheet</td>
<td>May 2013</td>
<td>Added and November 2012 deleted.</td>
</tr>
<tr>
<td>1 – Inability to carry out statutory remit</td>
<td>Cause and effects</td>
<td>Clarified timing of Member re-appointments.</td>
</tr>
<tr>
<td>1 – Inability to carry out statutory remit</td>
<td>Existing controls</td>
<td>Staff survey action plan now in place.</td>
</tr>
<tr>
<td>1 – Inability to carry out statutory remit</td>
<td>Actions to improve mitigation</td>
<td>Action regarding job evaluation more specific.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Staff survey action plan now in place.</td>
</tr>
<tr>
<td>2 – Failure to manage change</td>
<td>Cause and effects</td>
<td>Succession planning clarified to contingency planning.</td>
</tr>
<tr>
<td>2 – Failure to manage change</td>
<td>Existing controls</td>
<td>Succession planning activity clarified. HTA/HFEA review now reported.</td>
</tr>
<tr>
<td>2 – Failure to manage change</td>
<td>Actions to improve mitigation</td>
<td>Timing of independent review work updated.</td>
</tr>
<tr>
<td>3 – Inability to manage a major event</td>
<td>Sources of Assurance</td>
<td>Living Donation Activity Report and Communications Evaluation Report added</td>
</tr>
<tr>
<td>5 – Inadequate stakeholder management</td>
<td>Existing controls</td>
<td>Special emphasis on communications with transplant community not needed now ODD in place.</td>
</tr>
</tbody>
</table>
Authority paper

Date  28 May 2013  Paper reference  HTA (33/13)
Agenda item  16  Author  Allan Marriott-Smith

Strategic Performance Review – April 2013

Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during April.

Action

2. Members asked to note the content of the report.

Decision-making process to date

3. The HTA Management Group has reviewed the content of this paper as part of its monthly monitoring of business plan delivery. This paper is provided to the Authority for information purposes.

Background

4. The Authority has agreed to monitor a set of KPIs that demonstrate whether the Human Tissue Authority’s (HTA) strategic aims are being delivered. This report presents results as of the end of April.
Progress in April 2013

Regulation

1. All reportable KPIs for the Regulation Directorate were green.

Strategy and Quality

2. All reportable KPIs for the Strategy and Quality Directorate were green.

Communications and Public Affairs

3. Of the four reportable KPIs in the Communications Directorate, three were green.

4. One KPI (KPI 2.3) is red. In April, 89% of enquiries were answered within 10 working days (against a target of 95%). Anecdotally we are aware that more cases are answered within deadline but are not recorded as such on our reporting system (CRM), which negatively impacts on the indicator. We are seeking to address this by reviewing how we categorise enquiries in CRM (to make enquiries simpler to record), reviewing the reminders sent when deadlines fall due, and considering any need for staff enquiry training.

Resources

5. The KPI for the Resources Directorate is not due to be reported until October 2013.

CEO

6. The vacancy rate (KPI 3.1) was red with an outturn of 6% against a target rate of 5%. There were 3 vacancies at the end of April 2013 for a Regulation Manager, a Website and Communications Officer and a Policy and Quality Manager.

7. KPI 3.2 relating to attrition was red, 21% against a target of 18% for the rolling year May 2012 to April 2013. There were 2 leavers in April, Fiona McKinson and Pamela Sandler.