Fifty-ninth Meeting of the Human Tissue Authority

Date 22 January 2013
Time 10.30 – 13.00
Venue The Westminster Conference Centre
1 Victoria Street
London
SW1H 0ET

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

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 27 November 2012 HTA (01/13)
4. Matters arising
5. Chair’s Report
6. Final update on the implementation of the Organ Donation Directive (I) HTA (02/13)
7. Regulatory oversight of Post Mortem microscope slides (I) HTA (03/13)
8. Consultation on the Human Transplantation (Wales) Bill (D) HTA (04/13)
9. Complaints Report (I) HTA (05/13)
10. Governance: Decision-making Framework (I) HTA (06/13)
11. Finance Report December 2012 (I) HTA (07/13)
12. Risk register January 2013 (I) HTA (08/13)
13. Strategic Performance Review December 2012 (I) HTA (09/13)
14. Any other business
Minutes of the fifty-eighth meeting of the Human Tissue Authority

Date  27 November 2012
Venue  Westminster Conference Centre
       1 Victoria Street
       London
       SW1H 0ET

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

Observers
Ms Morounke Akingbola (Head of Finance and Governance) 
Ms Jo deBank (Media and Communications Officer) 
Ms Stephanie Etherson (Administrative Assistant) 
Mrs Nicola Fookes (Finance Manager) 
Ms Dawn Pike (HR Adviser) 
Ms Katharine Tinker (Transplant Officer) 
Mr Patrick Irwin (Department of Health) 
Mr Ted Webb (Department of Health)
<table>
<thead>
<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
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<tr>
<td>Item 1</td>
<td>Welcome and apologies</td>
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<tr>
<td>1.</td>
<td>Baroness Warwick welcomed Members and observers to the fifty-eighth meeting of the Human Tissue Authority (HTA).</td>
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<td>2.</td>
<td>Apologies had been received from Professor Susan Dilly.</td>
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<td>Item 2</td>
<td>Declarations of interest</td>
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<td>3.</td>
<td>Mr Keith Rigg declared an interest in item 7 on licence fees for 2013/14 as he works at a licensed establishment.</td>
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<td>Item 3</td>
<td>Minutes of 10 July 2012 [paper: HTA (47/12)]</td>
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<td>4.</td>
<td>The minutes of 25 September 2012 were adopted.</td>
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<tr>
<td>Item 4</td>
<td>Matters arising</td>
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<td>5.</td>
<td>A note addressing matters arising was circulated to Members on 20 November.</td>
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<td>6.</td>
<td>Information on the HTA’s plans for collaborative working are addressed in the paper supporting item 14 on the Arm’s Length Bodies (ALB) review.</td>
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<td>7.</td>
<td>A breakdown of the types of procurement Serious Adverse Events and Reactions (SAEARs) was circulated to Members on 20 November.</td>
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<td>8.</td>
<td>Entrance interviews had been conducted with five new starters between April and October 2012. All those interviewed had a positive prior knowledge of the HTA and believed the work they would be doing was important, interesting and would have impact. Aspects of the HTA website and induction pack were identified as areas for improvement and both are being addressed. There are no plans to continue formal entrance interviews, however, new starters meet with the Chief Executive during their first week and any themes which are identified in these meetings will be addressed.</td>
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<td></td>
<td>Action: The HTA website to be discussed at the next Communications Members’ Group</td>
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<td>Item 5</td>
<td>Chair’s report</td>
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<td>9.</td>
<td>Since the last Authority meeting staff at the HTA have received training in the following areas:</td>
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<td>9. Complaints handling</td>
<td>b. Data Protection Act and Freedom of Information Act</td>
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<td>c. Crisis management and crisis communications</td>
<td>d. Equality and diversity.</td>
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10. Meetings have been held with:
   a. GE Healthcare; and
   b. Peter Thompson, Chief Executive of the Human Fertilisation and Embryology Authority (HFEA)

11. Alan Clamp, Diana Warwick and Shaun Griffin met with His Honour Judge Peter Thornton QC, the Chief Coroner.

12. Alan Clamp attended a strategy breakfast meeting at the Care Quality Commission (CQC).

13. Alan Camp attended a workshop for Chief Executives at the Department of Health (DH) which aimed to align the priorities of ALBs with DH. Diana Warwick attended the equivalent meeting for Chairs.


15. On the 17 October the HTA held a parliamentary surgery at the House of Commons. Earl Howe gave a brief speech and complimented the HTA on its work and the efforts of its staff. Since the event a briefing has been sent to all Parliamentarians with an interest in the HTA’s work. A number of stakeholder groups attended as did several Parliamentarians.

16. The HTA has attended a number of meetings with the Welsh Government and more information is provided in the paper supporting item 8.

17. The Audit Committee met on 14 November and a report of this meeting is at item 13.

18. The Policy and Regulatory Activity Group (PRAG) met on 14 November, and items discussed included:
   a. The Regulatory Activity Report which is at item 10.
   b. The Living Donation Activity Report which is at item 11.
   c. The HTA’s plans in regard to post mortem microscope slides.
   d. The renaming of Serious Untoward Incidents. It is planned these will become HTA Reportable
Incidents.

e. Items c and d above will be discussed by the full Authority in due course to reach a final decision.

19. There has been a good deal of coverage in the Jewish Chronicle on the Welsh Government’s plans to introduce an opt-out system for organ donation. There have been articles and letters in most recent editions of this newspaper and in other Jewish publications. It was suggested that the HTA assess whether there has been any coverage of this issue in the Muslim and Catholic press.

20. Diana confirmed that she had been reappointed as Chair of the HTA for a further year (until January 2014). It was disappointing the reappointment was not for longer, as a single year term may suggest to stakeholders and staff that there could be changes to the HTA as early as 2014, when in fact the possible transfer of functions would not happen before 2015.

21. As yet DH had not confirmed whether the four Members whose terms end in March 2013 would be reappointed. Discussions on this matter are on-going. Concern was expressed as to how well the Authority would be able to function, were they not to be re-appointed, at just eight Members, both as a Board and also in regard to the statutory requirement of assessing a cohort of living organ donation cases.

**Action:** To provide feedback on the extent of coverage of the Welsh Government’s plans on an opt-out system for organ donation in the Muslim and Catholic press

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<tr>
<th>Item 6</th>
<th>Substances of Human Origin – Vigilance and Surveillance project [paper: HTA(48/12)]</th>
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<tr>
<td>22.</td>
<td>Elvira Manjaji introduced the paper, which provided Members with an update on the conference the HTA is organising as part of the Substances of Human Origin – Vigilance and Surveillance (SoHO V&amp;S) project.</td>
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<td>23.</td>
<td>The project started in 2009 and is led by the Italian Competent Authority.</td>
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<td>24.</td>
<td>The conference will be held on 18-20 February 2013 and Members were invited to attend on either the 19 or 20, or on both days.</td>
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<td>25.</td>
<td>The Authority noted the content of the paper.</td>
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**Action:** Members to contact Vicky Marshment to confirm attendance
### Item 7  Licence fees 2013/14 [paper: HTA(49/12)]

26. Sue Gallone introduced the paper which provided Members with an overview of the licence fees proposal for the year 2013/14. A presentation was given to provide further detail and illustrate the options available to the HTA in regard to fees.

27. This year the fees modelling had been done in-house, building on PA Consulting’s previous work in this area.

28. DH has confirmed that fees for the transplantation sector will be subsidised during 2013/14.

29. There will be a further 10% reduction in the amount of Grant-in-Aid (GIA) the HTA receives.

30. The modelling was undertaken on the basis that there will be two fewer posts next year. However, due to maternity leave, there may be need to fill one of these and this had been taken into account.

31. The NHS Litigation Authority (NHSLA) has expressed an interest in using some of the spare desk space at the HTA office, which would bring in extra income.

32. It was recommended that £3.4m is recovered in fees for 2013/14.

33. It was noted that the £3.4m figure is challenging, however it was hoped that by setting a tight figure, in the sense that it the figure would allow little room for variation, fees would be fair and there would be no need to issue rebates.

34. It was suggested that consideration be given to communicating what the fee level would have been for the transplantation sector without the subsidy, in order that the sector can prepare to secure funding for 2014/15.

35. The Authority accepted the £3.4m level for fees for 2013/14 and agreed the fees for each sector.

**Action:** To consider communicating what the fee level would have been for the transplantation sector for 2013/14

### Item 8  Update on Welsh Government’s legislation on an opt-out system for organ donation [paper: HTA(50/12)]

36. Allan Marriott-Smith introduced the paper which provided an update on the Welsh Government’s plans and a likely timeline.

37. The legislation to introduce an opt-out system for organ donation was laid on 4 December and it is expected that Royal Assent will be given in July or August 2013.
38. DH has confirmed that it will lead on any changes which will need to be made to the Human Tissue Act 2004.
39. A teleconference was held with Welsh officials on 26 November when it was agreed that a working group would be established to draft guidance for those seeking consent in Wales and the rest of the UK. The HTA will be part of this working group. It is planned that this guidance will lead to redrafted Codes of Practice to be published during the 2014/15 business year.
40. There was discussion on the issues where there was still a lack of clarity, including how it will be established a person has been resident for six months and arrangements for the registration of wishes.
41. There was concern that, by seeking to reflect the two systems of consent in one Code of Practice, the HTA may appear confused and contradictory, and as such consideration should be given to publishing two separate documents.
42. The Authority noted the content of the paper and agreed that further work would be required before any position statement could be issued.

**Action:** For the Welsh Government’s proposals and the HTA’s role to be discussed further at the January 2013 Authority meeting

### Item 9 Strategic Plan 2013 to 2016 – sign off [paper: HTA(51/12)]

43. Allan Marriott-Smith introduced the Plan, which had been discussed at the away day in September.
44. It was agreed that strategic aim one should read “further improve”, rather than just “improve”.
45. The Authority approved the amended strategic plan.

**Action:** To change strategic aim one to read “further improve”

### Item 10 Regulatory Activity Report – July to September 2012 [paper: HTA(52/12)]

46. Imogen Swann introduced the report which had previously been discussed at the PRAG meeting in November.
47. An establishment in the Human Application sector had failed to meet all the requirements of Directions issued during quarter one. In light of this the new decision framework had been used and a decision was taken to suspend processing, vary the licence and place a restriction on the use of a particular testing facility.
Communication with this establishment continues in order to ensure that all requirements are met.

48. The Competent Authority for the Human Application sector in Germany had invited the HTA to undertake a joint inspection of the company which has been accused of importing material procured without consent. The joint inspection will take place in early 2013.

49. Four pilot audits had been conducted in the transplantation sector and feedback from these will be used to inform the full audit process. Two workshops had been held to provide the sector with information on audits.

50. A notification has been sent to all Corporate Licence Holders and Designated Individuals (DIs) to remind them of the need to notify the HTA promptly of the replacement of a DI.

51. It was noted that there had been an increase in the number of Serious Untoward Incidents (SUIs) between quarters one and two (11 to 19) and further information on this would be provided at the next Authority meeting.

52. It was asked whether the HTA inspects those establishments which are identified in contingency plans, especially in the post mortem sector. It was confirmed that the HTA recommends that a Service Level Agreement is in place and questions are asked on this during inspection.

53. The Authority noted the content of the report.

**Action: To provide an update on the increase in SUIs between quarters one and two**

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<thead>
<tr>
<th>Item</th>
<th>Living Donation Activity Report – July to September 2012 [paper: HTA(53/12)]</th>
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<tr>
<td>54.</td>
<td>Allan Marriott-Smith introduced the paper, which had been discussed at the PRAG meeting in November.</td>
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<td>55.</td>
<td>There was an update of the possible revision of Code of Practice two on solid organ donation and whether amendments could be made to this without parliamentary approval. The Code of Practice currently infers that directed altruistic donation is unlawful. The worst case outcome that could result is that it may prevent a person from receiving an organ. Therefore, the decision had been taken to place an amended version of the Code of Practice on the website, to mitigate against this risk. The Organ Donation Directive (ODD) will also be reflected in the amended version.</td>
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56. As the Regulations which implemented the ODD are being revisited, DH had proposed that an amendment be made to reinstate the HTA’s ability to designate a person who can legally supply organs for reward.  
57. The Authority noted the content of the report.  

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<tr>
<th>Item 12</th>
<th>Strategic risks [paper: HTA(54/12)]</th>
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<td>58. Sue Gallone introduced the paper. She advised that the Audit Committee had considered the Authority’s risk report and believed that it gave assurance on the management of risks. The Committee has concluded that this document should be used by the Executive and escalated to the Audit Committee as necessary.</td>
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<td>59. It was queried whether this report created duplication. However, it was noted that the emphasis of the strategic risk register and the Authority risk report were different and that both contribute to risk management.</td>
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<td>60. The Authority noted the content of the paper.</td>
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<tr>
<th>Item 13</th>
<th>Report of the Audit Committee November 2012 [paper: HTA(55/12)]</th>
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<td>61. Catharine Seddon introduced the report, which gave Members an update on the November Audit Committee meeting.</td>
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<td>62. It was confirmed that the Authority risk report provided the Audit Committee with sufficient assurance, and a periodic review of the report by the Senior Management Team (SMT) had been recommended.</td>
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<td>63. A discussion had taken place on the risks in the Strategy and Quality Directorate with particular focus on the Independent Assessor (IA) system. The Audit Committee was pleased to learn that all those invited to the enhanced IA training in July had attended and that there had not been any recent resignations from the role. A more thorough review would be undertaken in 2013.</td>
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<td>64. All reports from the Internal Auditors had been marked as green.</td>
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<td>65. It was agreed that Members had been very pleased with the service and professionalism offered by Grant Thornton and that it was hoped that DH’s current tendering process provides a similarly satisfactory service for the HTA.</td>
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<td>66. It was further agreed that this should be communicated to DH.</td>
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<tr>
<td>Item</td>
<td>Report/Consultation</td>
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| 14   | ALB review consultation update [paper: HTA(56/12)] | 68. Alan Clamp introduced the paper which updated Members on the ALB Review consultation.  
69. Further work had been done on the potential efficiencies which could be made through more radical models of collaboration but the savings identified were relatively small.  
70. There were plans for the NHSLA to use some of the HTA’s spare office space which would generate income, and discussions on collaborative working with the HFEA continue.  
71. The Authority noted the content of the paper. |
| 15   | Finance Report October 2012 [paper: HTA(57/12)] | 72. Sue Gallone introduced the report which provided members with an update on the financial position as of 31 October 2012.  
73. In regard to the spend on legal advice, this had been steady in contrast to the previous two years when there had been significant and unexpected additional spend requirements.  
74. The position in regard to debtors was much improved from the previous year, with only four debtors remaining from the 2011/12 business year, and an additional four from the April 2012 invoice round.  
75. The Authority noted the content of the paper. |
| 16   | Strategic Performance Review October 2012 [paper: HTA(58/12)] | 76. Allan Marriott-Smith introduced the paper which updated Members on the progress against Key Performance Indicator’s (KPI’s).  
77. The project to improve the HTA’s enquiries handling was marked as amber, although this was still within tolerance and was now making good progress as the Communications Directorate was now fully staffed.  
78. There were two Regulation Manager and one Assistant posts vacant at the end of October, meaning the vacancy rate was marked as red.  
79. The Authority noted the content of the paper. |
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<tr>
<th>Item 17</th>
<th>Any other business</th>
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<td>80. A joint HTA and Professional Standards Authority (previously Council for Healthcare Regulatory Excellence) event was planned for 11 December focusing on consent issues. The attendees represent the public and public facing groups. Diana Warwick and Pamela Goldberg would be attending for the Authority.</td>
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The meeting closed at 11.45am
Final update on the HTA’s implementation of the requirements of the European Directive on standards of quality and safety of human organs (2010/53/EU)

Purpose of paper

1. To update the Authority on the successful implementation of the Directive.

Action

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

Decision-making process to date

3. This paper is for information and the contents have not required any decisions to be made.

Progress

4. We have delivered two further workshops in the period since the November 2012 Authority meeting, one in London on 28 November and the second in Manchester on 6 December. Every establishment that is now licensed by HTA was represented by a delegate.

5. The workshops covered topics such as preparing for an audit, information about regulatory processes (for example, actions that might follow an inspection), and the reporting of serious adverse events and reactions (SAEARs).

6. The workshops engendered a spirit of constructive dialogue and debate and were well received by delegates. It was interesting to note that a number of
delegates expressed the view that they could see some potential benefits arising from the new regulations, particularly in terms of raising and harmonising standards and sharing good practice.

7. On 6 February we will be running a final workshop specifically for staff working under NHS Blood and Transplant’s (NHSBT) licence.

8. All 35 establishments issued with a fixed term licence in August have, following a full assessment of their licence application, been issued with a continuous licence.

9. Of those 35, 15 are being asked to complete a corrective and preventative action plan to address shortfalls identified during the assessment process, the most common shortfalls relate to a lack of documented procedures.

10. We have started scheduling audits and six audits have been confirmed between now and the end of the business year.

**Review of Organ Donation Directive (ODD) Project**

11. In December a meeting was held to review the ODD project; the meeting was attended by work package owners and other contributors to the project. Attendees were asked to consider

   - What went well?
   - What could we have done better?
   - What were the key learning points?

12. This was a significant and sustained project for the HTA that drew upon resources across the organisation. Successful delivery of the project also required successful collaborative working with a number of key stakeholders including the Department of Health (DH), NHSBT and professional representatives from the sector.

13. The project consisted of 11 work packages and ran over an 18 month period.

**What went well?**

14. There was general agreement that we had successfully negotiated a statutory instrument and associated Framework that was proportionate, practical and that met the requirements of the Directive.
15. There had been good engagement with the sector throughout, and this cycle of engagement and feedback significantly influenced our ability to develop a regulatory framework that would be fit for purpose.

16. Allocating a portfolio of establishments to a group of Regulation Managers resulted in the efficient assessment and processing of licence applications. Consistency of licensing decisions was enabled by the establishment of a peer review group.

17. Regular communications with NHSBT facilitated a successful outcome regarding the conclusion of a service level agreement to underpin the delegation of certain functions to NHSBT.

18. Similarly, developing good working relationships with key people at NHSBT and building on the openness between organisations was central to the development of the SAEARs guidance document.

19. The pilot audits were essential to informing our audit strategy and enabled us to deliver informative workshops on how an audit would be conducted. The pilots also informed the development of an audit guidance document.

20. IT development of the existing CRM system for licence applications and SAEARS was flexible, responsive and met challenging deadlines.

21. There was good communication via the media and the HTA’s website.

**What could we have done better?**

22. Early consideration and understanding of the political, cultural and resource constraints of external contributors to the project would have enabled better horizon scanning of potential delays and snagging points. This in turn would have improved our ability to manage and mitigate against delays.

23. In retrospect, it would have been beneficial to have allocated and engaged internal legal support at an earlier stage of the project. This would have assisted in the development of the project plan, particularly in synchronising key deliverables with the legislative process, and it would have had the additional benefit of helping to identify legal concerns earlier on in the project.

24. Timelines for reviewing and amending key documents were not always realistic.

25. There was an over-reliance and confidence in the ability of external organisations to provide a definitive list of transplants centres which would
require a HTA licence. A consequence of this was that we did not correctly identify all potential licencees early on in the project.

26. The ‘domino’ effect of changes to one work package on another work package had not always been accurately identified.

**Key Learning Points**

27. Specific considerations need to be taken into account when running a project involving the contribution and input of external organisations. In particular, a good understanding of the organisations, alongside regular communications and engagement are essential to ensuring successful delivery.

28. Realistic processes, resources and timeframes for review of key documents and deliverables should be built into a project plan. Consider limiting the number of people involved in the review and quality assurance processes.

29. Identify and validate a stakeholder list at the outset of a project.

30. Identify interdependent work packages and take into account the ‘domino’ effect of changes to related work packages.

31. Identify legal resource requirements from the outset of a project.

32. Conduct an overall ‘resource’ analysis at the outset of a project and build in some contingency.

**Conclusions**

33. This was a challenging project for the HTA, undertaken during a period of change and uncertainty and an increasing impetus set by Government to demonstrate a reduction of regulatory burden in the healthcare sector. Against this backdrop the project also saw a significant number of project team members leave the HTA during its lifetime, coupled with a number of changes made to the composition of Senior Management Team (SMT) members. Additionally, keeping the project on task and meeting all key milestones against a backdrop of uncertain and frequently changing legislative procedural timelines was particularly demanding and challenging.

34. Despite the significant challenges of this project, we have achieved considerable success in developing an effective framework for the regulation of organ transplants. A number of high quality documents have been produced to support the framework, the contents of which have involved the contribution of
many people both internally and externally. Everyone involved has demonstrated commitment to a positive outcome.

35. At the outset of the project there was significant resistance from the sector to the new regulations, that resistance appears to have shifted and we have now established a constructive dialogue with these new stakeholders. This shift has been achieved by ensuring good engagement and demonstrating a willingness to listen to stakeholders concerns and adjusting our approach where there has been scope to do so.

36. The excellent outcomes from this project have been achieved by a strong supportive corporate culture and a willingness of HTA staff to go the extra mile when needed.

**Developing a strategy for 2014/15**

37. During the third quarter of the 2013/14 business year a review will be conducted of the 26 audits that will have been undertaken by the end of August 2013. The review will be used to inform the future strategy for auditing this sector, which in turn will inform the fee strategy for the business year 2014/15. The Authority will be informed of the outcome of the review and be provided with recommendations regarding our future strategy.
Authority paper

Date 22 January 2013
Agenda item 7
Paper reference HTA (03/13)
Author Caroline Browne

Regulatory oversight of Post Mortem microscope slides

Purpose of paper

1. To inform the Authority about the HTA’s revised approach to Post Mortem (PM) microscope slides, planned for implementation in the new business year (2013/14).

2. To provide assurance to the Authority that this approach has been fully considered, including any potential risks.

Action

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

Decision-making process to date

4. The revised approach to our regulatory oversight of microscope slides has been discussed in detail by the Histopathology Working Group (HWG), which includes Authority Members, and the Policy and Regulatory Activity Group (PRAG); input from these groups has informed its development. The project to implement the recommendation has been discussed by the HTA Management Group (HTAMG) and approved by the Senior Management Team (SMT).

Background

5. In September 2011, members of the HWG raised concerns about the HTA’s regulatory requirements in relation to traceability of microscope slides, which they felt were disproportionate, time consuming and costly. The HTA agreed to look at this issue and consider whether there might be an alternative way of assuring itself that this
tissue is managed in accordance with statutory requirements. A detailed paper outlining a new approach, which had been agreed in principle by SMT, gained support at the next meeting of the HWG in March 2012 and a project initiation document and project plan was subsequently approved by the HTAMG.

6. The paper proposed that, when undertaking traceability audits on a sample of cases on inspection, the Regulation Manager (RM) will check that the number of slides stored matches the number recorded as having been made, reporting any discrepancies to the Designated Individual to follow up, but will not check records for disposal details of microscope slides. Instead, more emphasis will be placed on the organisation’s policy and procedures on disposal and its internal audit systems.

7. This does not mean allowing slides to be retained without consent, microscope slides contain relevant material and are subject to the same consent and licensing provisions as any other material, but rather assuring ourselves through review of policies, operating procedures and the establishment’s own audit activities that systems are in place to prevent unauthorised tissue storage and use.

8. This revised approach recognises the difficulties faced by the sector and shows that we have responded to them in a proportionate fashion, without compromising our commitment to fulfilling our statutory responsibilities. There is no change in the requirements to obtain consent under the Human Tissue Act 2004 (HT Act). What is changing is the way the HTA monitors compliance by each licence holder. The HTA takes account of its own statutory duty under section 38 HT Act, under which ‘regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed’.

9. The change will necessitate minor amendment of the disposal code and standard D2, which be undertaken as part of the project.

10. At the meeting of PRAG in November, Members present were provided with an explanation of the reasons for the change and the practical implications, including the detail of the necessary amendment to the code of practice on disposal and standard D2. Members were supportive and considered it to be proportionate and in line with our business objective to reduce regulatory burdens. However, they raised concerns that, by relaxing our oversight of microscope slides, we may increase the risk of these tissue samples being retained without consent and not identify this during site visit inspections. They asked that we consider this risk ahead of the January 2013 Authority meeting.
Risk

11. Our operational risk register identifies the risk of us not identifying shortfalls or non-compliances on inspection. We are already taking a range of actions to mitigate this risk, including:

a. training RMs to common standards and providing on-going refresher training
b. undertaking themed inspections on low-risk establishments only and assigning only experienced RMs to these
c. including review of consent procedures and consent documentation in all inspections of PM establishments
d. continuing to engage with licensed establishments through the provision of advice and guidance, ensuring we are ‘visible’ between site visit inspections
e. requiring establishments to submit two-yearly compliance updates.

12. In addition to these actions, we are introducing a range of new ‘examples of evidence of compliance’ against HTA standards on traceability and disposal, which will test establishments’ systems of tissue governance.

13. We are also developing our risk profiling, seeking to make better use of the information we have available to us on our licensed establishments, and introducing new methods for quality assuring RM’s evidence gathering and regulatory decision making.

14. We believe that these steps will mitigate the risk of unauthorised tissue retention. However, to provide further assurance, the HTA will review practice relating to microscope slides after the revised approach has been in place for a 12 month period. This may be through our inspection process, a compliance update or directions requiring establishments to undertake a sample audit and report back to the HTA on their findings, and will be considered in next year’s round of business planning.

In summary

15. It is six years since the commencement of the HT Act. We have worked hard during this time to make stakeholders aware of the statutory requirements, to ensure that they are understood and, through our inspection programme, to provide assurance that they are being met.

16. We are satisfied that licensed establishments, and the professionals working within them, are aware of the need to ensure that, following a coroner’s or hospital PM examination, tissue is not stored or used for scheduled purposes without consent, and that to do so knowingly would be unlawful. However, we also need to assure ourselves that systems are in place to prevent unauthorised tissue storage, and we require that
the effectiveness of these systems can be readily demonstrated. Doing so ensures that the public can be confident in activities undertaken by licence holders.

17. Systems governing tissue retention remain of primary importance to ensure that tissue of any kind is not retained without consent. If, on inspection, we find that these systems are not adequate and that there is a risk of unauthorised tissue retention, we will look into this further; where shortfalls are found, we will take appropriate regulatory action.

18. The HTA is committed to acting in line with the five principles of better regulation: to be proportionate; accountable; consistent; targeted; and transparent. In addition, the Regulators’ Compliance Code recommends that regulators consider and take into account the impact that their regulatory interventions may have on regulated entities.

19. This new approach recognises the improvements in standards in the sector, whilst enabling the HTA to continue to fulfil its statutory duty to prevent tissue samples of whatever nature being kept and used without consent. It may also serve to reduce the regulatory burden on establishments, which are currently struggling to comply with the standard to record the fate of each individual microscope slide. We believe that it demonstrates our proportionate approach to regulation.

Timetable

20. Implementation is planned for the beginning of the next business year (2013/14) following a period of preparation by HTA staff and communication with the sector, in line with a project plan. The work will be led by the Regulation Directorate, working closely with the Communications Directorate.
Authority paper

Date 22 January 2013  Paper reference HTA (04/13)
Agenda item 8  Author Victoria Marshment

HTA response to the National Assembly for Wales’ Health and Social Care Committee’s consultation on the Human Transplantation (Wales) Bill

Purpose of paper

1. To provide the Authority with information on the progress of the Human Transplantation (Wales) Bill which seeks to introduce an opt-out system for organ and tissue donation in Wales.

2. To seek sign-off of the consultation response included as an Annex.

Action

3. The Authority is asked to comment on and sign-off the consultation response included as an Annex.

Decision-making process to date

4. The Authority has discussed the proposal to introduce an opt-out system in Wales at various stages of the proposal’s development over the past two years and has signed-off responses to two consultations on this matter.

5. The consultation response included as an Annex to this paper has been discussed by the Senior Management Team (SMT), it has not been discussed by the full Authority or any sub-group.
Background

6. Over the course of the last two years the HTA has contributed to the various consultation exercises run by the Welsh Government and other bodies on plans to introduce an opt-out system for organ donation.

7. The HTA had an observer role on the expert group which was convened to aid the development of the Welsh Government’s proposals.

8. The HTA sits on the Wales Transplantation Advisory Group, which provides advice and guidance on a broad range of transplantation and donation issues, and is not specifically focussed on the introduction of an opt-out system.

9. The HTA is also part of the Human Transplantation (Wales) Bill Working Group. This group first met on 16 January 2013 and will work together to provide guidance on the practical issues flowing from the Bill. It is currently envisaged that this guidance will eventually form part of a Code of Practice.

Consultation of the Health and Social Care Committee

10. This consultation is being undertaken by the Health and Social Care Committee of the National Assembly for Wales, and as such forms part of the scrutiny process of the proposed legislation.

11. Alan Clamp, Chief Executive of the HTA, will give oral evidence to the Committee on 30 January 2013.

Role of the HTA

12. The Bill requires the HTA to give practical guidance in its Codes of Practice on deemed consent. This is only in regard to the Codes of Practice where this is relevant, namely those which address matters of removal and storage.

13. The Bill also requires the HTA to superintend the Human Transplantation (Wales) Act.

Timetable

14. The HTA’s response will be submitted on the morning of 25 January 2013, taking into account any amendments required following the Authority meeting on 22 January 2013.

15. The Committee intends to issue its report on the Bill by 22 March 2013.
16. The Welsh Government envisages the Bill gaining Royal Assent during the summer of 2013.

17. The opt-out system will become operational in 2015.
HTA (04/13) Annex

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Health and Social Care Committee’s consultation on the Draft Human Transplantation (Wales) Bill (the Bill).

2. As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), the HTA is charged with ensuring that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.

3. The HT Act covers England, Wales and Northern Ireland and requires consent for a number of activities, including organ donation, to be an active and positive act.

4. There are similar provisions in Scotland under the Human Tissue (Scotland) Act 2006, and while the word “authorisation” is used in place of “consent”, there is a requirement that this is a positive act and the principle is the same.

5. This response is in regard to the Welsh Government’s proposal to introduce an opt-out system for organ donation in Wales. The essence of the proposal is that for people who both live and die in Wales and who did not make a decision in life on organ donation, the presumption will be that they wished to donate their organs and tissue after death.

6. The HTA has responded to previous consultations on the introduction of an opt-out system for organ donation, these responses can be found here.
The proposal

7. It is of value to set out the main features of the Welsh Government’s proposals in order to place this response in context.

8. The Bill introduces the concepts of deemed and express consent. Express consent is identical to the active consent requirement of the HT Act. It is, in the first instance, the consent of the person themselves in life, if that does not exist the consent of an appointed representative, and if there is not a representative, then the consent of a person in a qualifying relationship to the donor.

9. Under the Bill express consent will be required for:

   a. Living organ donation
   b. Deceased organ donations from children
   c. Deceased organ donations from adults who lack the capacity to consent
   d. Deceased donations from people who live and die in Wales but have not been resident for six months or more
   e. Deceased organ donations from people who die in Wales but who are not resident in Wales
   f. Deceased organ donations from Welsh residents who die somewhere else in the UK

10. Under the Bill, when an adult Welsh resident who had the capacity to consent dies in Wales, and had registered either a wish to be considered as an organ donor, or their wish not to be an organ donor, this will be acted upon, if possible.

11. If such a person has not registered either a yes or a no, then their consent will be deemed. This means that the starting point of the conversations which will be held with the potential donor’s family and friends is that they wished to donate. At present, when there is no recorded wish the family are approached to ask whether they are aware of the wishes of the deceased.

12. The fact that the family will still be involved in the process under the Welsh Government’s proposals means that this key safeguard remains in place. Although the family will not have the right to veto the donation if a recorded yes is in place or consent is deemed, if they are able to provide evidence that would satisfy a reasonable person that the deceased did not wish to be a donor this will be accepted.
13. If a person has recorded a no, their family will be informed of this. If a document signed by the deceased, and which post-dates the recorded decision to opt-out, is presented by the family, then donation might be considered.

14. It should be noted that the current legislation (the HT Act) does not give families a veto over the deceased’s recorded wishes. When a person has registered on the Organ Donor Register (ODR), and subsequently dies, the role of the family is to let the Specialist Nurse for Organ Donation (SNOD) know whether they had changed their mind, and to provide the medical and social information necessary for a decision to be made on whether donation should go ahead. The existing legislation does not make provision for a family to stop a donation because they do not want it to go ahead.

15. In reality, however, the duty of care the surgical and medical teams have to the family of the deceased means that a donation will not usually proceed without their support. This matter is coming to the fore in discussions on deceased donation rates across the UK. The HTA has engaged and will continue to follow with interest this discussion.

16. The HTA acknowledges that there are areas which require further consideration prior to the implementation of the proposed system. However, the operational process as laid out in the explanatory memorandum does not differ significantly from that which operates at present, in the sense that the register will be consulted and a conversation will then be held with the family.

17. What will change is that there will be a new register which will record both wishes to donate and wishes not to donate, and that where the deceased had not made a decision in life, their family would be approached on the basis that they wished to be a donor.
The role of the HTA

18. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Welsh Government, which is constituted of the elected representatives of the Welsh people.

19. It is the role of the HTA to provide advice and guidance as required, and this document seeks to provide a detailed response to the areas highlighted in the Committee’s letter of 6 December 2012 and other issues for consideration by the Committee. This advice and guidance is based on the experience the HTA has gained since it was established in 2005, and on the provisions of the HT Act as it currently stands.

20. The HTA notes the ethical discussions on the Welsh Government’s proposals. However, as a statutory regulator it is outside the remit of the HTA itself to participate directly in such discussions.
Response to terms of reference of the inquiry

21. In its letter of 6 December 2012 the Committee outlined the terms of reference for the inquiry and the HTA has addressed those within its remit below.

The individual provisions set out in the Bill:

Section 2, relating to the promotion of transplantation

22. The HTA has no comments in regard to section 2 of the Bill.

Section 3, relating to lawful transplantation activities

Licensing

23. Under the HT Act a licence is required for two of the activities listed in section 3, these both relate to storage and are included at s.3(2)(a)and(c) of the Bill.

24. The HT Act requires consent (as laid out in section one of the HT Act) for each of these storage activities and as such a licensed establishment must demonstrate that consent is in place as part of the HTA’s licensing requirements.

25. Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 a licence is required for the removal or implantation of an organ. A licence granted by the HTA under these Regulations also requires that HT Act consent is in place.

26. The Welsh Government and the Department of Health will need to make the changes required to the HT Act and Quality and Safety of Organs Intended for Transplantation Regulations 2012 to facilitate the licensing of these activities where consent has been deemed.

Relevant material

27. There is value in noting that section 3 of the Bill refers to “relevant material” rather than just organs. Relevant material is defined at section 16 of the Bill and means “material, other than gametes, which consists of or includes human cells”. Relevant material does not include “embryos outside the human body” or “hair and nails from the body of a living person”.
28. At present the Welsh Government’s plans in regard to deemed consent only address solid organs, however, the Bill provides scope for the transplantation of any relevant material to be lawful with deemed consent. This means that there would be no need for the legislative process to be undertaken to introduce deemed consent to the transplantation of other relevant material.

Import and export

29. Under section 41 of the HT Act the following definitions for import and export are provided:

a. “Import” means import into England, Wales or Northern Ireland from a place outside England, Wales or Northern Ireland.

b. “Export” means export from England, Wales or Northern Ireland to a place outside England, Wales or Northern Ireland.

30. Section 3 of the Bill suggests that it is the intention of the Welsh Government that the definitions at section 41 of the HT Act will no longer remain and in fact relevant material of the kind mentioned in s.3(2)(c) or (d) will be considered imported if it originates from any jurisdiction outside Wales.

31. If this is the intention it will be of vital importance for the Welsh Government and NHS Blood and Transplant (NHSBT) to work together to remedy any impact this would have on the allocation and use of deceased donor organs across the UK.

32. Amendments may also be required to the HT Act to ensure consistency between this and the Welsh legislation.

Section 4-8, relating to consent

Registration of wishes

33. The HTA notes the information provided in the Explanatory Memorandum and Privacy Impact Assessment on the proposed system by which Welsh residents will be able to register their wishes.

34. The HTA further notes that specifying such a system in primary legislation would restrict any changes or amendments that are required to the system in the future. However, without firm assurances as to the system which will be introduced to allow Welsh residents to register their wishes, it is difficult to assess how the process of establishing or seeking consent will differ from that which currently exists.
35. The establishment or seeking of consent are complex matters and involve communication with people in a period of high emotion. It will be key that any move to a system of deemed consent does not add further complexity and all involved in the process, including clinicians and the family, are informed fully of their role and responsibilities.

36. The HTA believes that a register which allows Welsh residents to both opt-in and opt-out of organ donation is necessary to guarantee that the wishes of the deceased in life remain paramount.

37. Such a register would allow the HTA to have greater confidence when drafting a Code of Practice including guidance on deemed consent in Wales, as the practical issues could be clearly addressed and advice provided on what steps should be taken in given circumstances.

38. The absence of such a register could, in the view of the HTA, increase confusion and uncertainty on the proposed system and could lead to the provision of advice and guidance by any organisation (including the HTA) being unclear and unhelpful.

**Living organ donation**

39. Under the provisions of the Bill, consent for living organ donation remains “express”, in that it is the consent of the individual. In practice it is difficult to imagine when consent to living organ donation could ever be anything other than express, although it should be noted that provision is made in both the Regulations\(^1\) supporting the HT Act and the Bill for living donors who are children or adults who lack the capacity to consent.

40. It is unclear to the HTA why living organ donation is included in the Bill, and on the face of it this inclusion adds complexity and confusion to no identifiable end.

**Section 9-11, relating to offences**

41. Under section 11, consideration should be given to being specific as to who should make a referral to the Director of Public Prosecutions.

42. From the HTA’s experience there is merit in policies and procedures being in place from an early stage in order that all involved understand their

responsibilities when an offence may have been committed. The Welsh Government may choose not to include this level of detail in the primary legislation; however, it should be available in good time for the proposed 2015 launch date.

**Sections 12-20, which make general provision**

43. Section 15(6)(b) of the Bill reads “after subsection (6) insert -”, the HTA believes this should read “after subsection (5) insert -“.

**Any potential barriers to the implementation of these provisions and whether the Bills takes account of them**

44. The HTA has no specific comments in regard to potential barriers to implementation.

**Whether there are any unintended consequences arising from the Bill**

45. The HTA has sought to address potential unintended consequences in relation to the sections of the Bill above.

46. In particular, please note paragraphs 23 to 26 above on licensing.

47. More generally, the HTA would further advise that agreed review periods are built into the post-launch programme to allow an assessment of the impact of the legislation. If the impact is a drop in the number of organs being donated, steps should be taken rapidly to understand the root causes.

48. Negative coverage of deemed consent in Wales could lead to mistrust in other parts of the UK, and it will be vital that this change does not adversely impact organ donation.

**The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact assessment), which estimates the costs and benefits of the implementation of the Bill)**

49. The table of fixed costs associated with the adoption of the opt-out system on page 45 of the Explanatory Memorandum details that spending on communications will fall in the period 2017-22 to £50k per annum, from a high of £1.453m in 2015-16.

50. The HTA believes that communication will be a vital element in the success or otherwise of the proposed system and would caution that £50k per annum
Authority Paper

Report on Complaints (January 2011- December 2012)

Purpose of paper

1. To provide a summary for the Authority on the complaints received by the HTA from January 2011 to December 2012 and how these complaints have been managed.

2. An enquiry is deemed to be a complaint if it is an allegation against the HTA about the way we have exercised, or failed to exercise, our functions. More information can be found in the HTA Complaints Policy (Annex A).

Action

3. The Authority is asked to note the content of this paper, provide comments on its format and to approve the recommendations at paragraphs 16-19.

Decision-making process to date

4. It is good practice for public bodies to report regularly on the complaints it has received and how these have been managed. This process supports effective complaints management and quality improvement. Complaints have been referred to in previous papers from the Communications Directorate but it was thought useful to have a separate annual report for Members. As this was the first report of its kind it covers a two year period from January 2011 to December 2012. Future reports will cover a single calendar year.

Background

5. From January 2011 to December 2012 the HTA received five formal complaints.
6. Formal complaints are defined as those that are referred to the Complaints Officer in writing. These relate to the work of the HTA. Complaints about other organisations or individuals are called ‘referrals’. The HTA also receives a number of informal complaints, such as complaints about the wording of inspection reports. Informal complaints are resolved without having to refer to the Complaints Officer or to record and handle these as per the HTA policy. It appears that there are few such informal complaints but from April 2013 these will be notified to the Complaints Officer in order that records can be kept and monitored.

7. A summary of each of the formal complaints received is provided below.

**Formal complaints**

**Complaint One**
8. On 31 January 2011, the HTA received a letter from a person expressing concerns about the importing of tissue into the UK for the purposes of exhibitions, stating that the HTA should take a more strict regulatory approach in this area. We responded with information about the HT Act, Codes of Practice on Public Display and Import and Export, and how the HTA regulates in these areas. We have heard no more from this correspondent.

**Complaint Two**
9. On 10 May 2011, the HTA received a letter from a Designated Individual (DI) who had taken over the role following significant regulatory action at the establishment in question. The DI sought reassurances that he would not be associated with previous non-compliance of standards. We provided information about the reasons behind the regulatory action and reassurances that this particular DI was considered suitable for the role and that we would provide support to address the areas for improvement identified. We have heard no more from this correspondent.

**Complaint Three**
10. On 4 July 2011, an establishment licenced by the HTA made a complaint about the initial decision of the Appeals Committee and the inspection carried out in February 2011. In August 2008 the establishment applied for a licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The HTA initial assessment was that the proposed Designated Individual (DI) did not meet the statutory requirements and a licence was not granted. The establishment made representations to challenge this and a hearing was held in October 2008. The hearing did not grant a licence as the HTA remained satisfied that the DI did not meet the statutory requirements. The establishment appealed and the Appeals Committee in February 2009 upheld the decision,
giving further information about the options for the establishment to challenge the decision. Subsequently, a fresh application for a new DI was made and a licence was granted.

11. The HTA inspected the establishment in February 2011 and on 4 July 2011 received the complaint as above. The complaint about the inspection referred to the conduct of the Regulation Managers and the judgements made. The HTA responded to the complaint of 4 July, upholding our inspection findings explaining that the decision of the Appeals Committee could only be challenged through judicial review. The HTA response was sent on 15 July 2011.

12. On 20 January 2012, the establishment sought a review of our handling of their complaint of 4 July 2011. We responded to them on 3 February 2012 confirming that having reviewed the decision our position had not changed.

13. The establishment then made a complaint to the Parliamentary and Health Service Ombudsman and were advised to revert back to us as they were seeking compensation and had not raised this previously with the HTA. On 13 June 2012 we received a further complaint from the establishment on the decision made by the Appeals Committee and the inspection, seeking compensation for the losses allegedly caused by the HTA and its actions. On 13 July 2012, the Director of Regulation responded to the establishment confirming that after a review of our decision and new evidence provided we were satisfied that we had made the right decision. An Authority Member also reviewed the complaint before the letter was issued and supported the Director’s findings. We have advised the complainant that we cannot deal with the same complaint again and have heard no more from this correspondent.

Complaint Four

14. On 21 May 2012, a DI made a formal complaint with regards to the untimely management of their Corrective and Preventative Action (CAPA) plan by one of our Regulation Managers following an inspection carried out on 21 July 2011. This complaint was forwarded to the relevant Head of Regulation and the Director of Regulation who investigated the complaint and upheld it. The Director responded to the complainant apologising for the delays. Internal procedures for monitoring CAPA plans have been strengthened following this complaint.

Complaint Five

15. On 19 October 2012 we responded to a complaint from a member of the public who was unhappy that the information on our website did not provide sufficiently clear information as to what would happen if medical schools could not accept the body of a deceased family member due to them having had a post-mortem
examination. The person’s father died at home and a post-mortem examination was carried out. As a result, the local medical school would not accept the body. The complainant had reported this to the HTA previously via the telephone but was not satisfied with the response and so submitted a formal written complaint. In our response of 19 October 2012, we apologised for the way the telephone call was dealt with. We also pointed out that we had since updated the Frequently Asked Questions on our website and that we would be providing updated information for medical schools to share with families, including advice on making contingency plans for when a body cannot be accepted by their local medical school. The issue was also discussed with the person who had taken the original telephone call. The correspondent responded to our letter thanking us for our actions.

**Recommendations**

16. All formal complaints continue to be logged onto the HTA complaints log on IMPACT and responses logged and tracked as cases in CRM. These will be reviewed quarterly at Senior Management Team meetings to identify lessons learned and actions required. Changes will be made to the complaints log to additionally record: (a) informal complaints resolved; and (b) lessons learned and action taken by the HTA.

17. The Complaints Officer will also review the feedback from inspections to capture and respond to any comments that might be construed as complaints.

18. The HTA Complaints Policy (Annex A) will be reviewed annually.

19. A qualitative and quantitative report in this format will be produced for Members in January each year.
Policy for handling complaints about maladministration and inappropriate conduct

1. Resolving complaints can improve the Human Tissue Authority’s (HTA’s) services and support the HTA’s reputation. In considering complaints the HTA applies the Parliamentary and Health Service Ombudsman’s (the Ombudsman) Principles of Good Administration, which are:

- getting it right
- being customer focussed
- being open and accountable
- acting fairly and proportionately
- putting things right
- seeking continuous improvement.

Purpose
2. This is the policy for handling complaints made by individuals or organisations about maladministration and inappropriate conduct by HTA staff or Members.

What does this complaint policy cover?

3. Complaints against the HTA rather than any other organisation, about the way it has exercised, or failed to exercise, its functions or provided a service.

4. This policy covers complaints about:
   - unprofessional behaviour, negligence, failure to carry out statutory functions or provision of an inadequate level of service
   - inappropriate behaviour or conduct, or incompetence of HTA staff or Members
   - failure to provide a service
   - delay that could have been avoided
   - failing to follow correct or appropriate procedures
   - not telling a person about any rights of appeal open to them
   - unfairness, bias or prejudice
   - giving advice which is misleading or inadequate
   - refusing to answer reasonable questions
   - rudeness and not apologising for mistakes
   - not putting things right when something has gone wrong.

5. The complainant must feel they have been disadvantaged or suffered harm because of a fault of the HTA.

What does this complaint policy not cover?

6. This policy does not cover complaints about:
• complaints against organisations within the HTA’s regulatory remit

• the HTA’s relationship between or with its employees

• contractual or commercial disputes involving the HTA

• matters that have become the subject of legal proceedings or are under police investigation

• complaints which have been investigated or are under investigation by the Ombudsman

• policy and other decisions made by the HTA under its statutory remit. Examples include:
  - setting licence fee levels
  - interpreting the Human Tissue Act
  - granting or refusing a licence
  - approving or refusing to approve the donation of an organ.

• third party allegations (including whistle blowing) against organisations within the HTA’s regulatory remit of non-compliance with the Human Tissue Act 2004 (the Act) or the HTA’s regulatory standards.

**Principles applied when handling complaints**

7. The principles the HTA will apply when investigating complaints about maladministration or mismanagement by the HTA or inappropriate conduct include:

• defining a complaint as any expression of dissatisfaction with administration or service

• publishing clear and transparent instructions to staff for reporting complaints

• trying to resolve complaints informally by responding appropriately on initial receipt, including providing an apology where required

• where complaints cannot be resolved, referring the complainant to the Complaints Officer who will arrange for an investigation at regular intervals

• informing complainants about the progress of the investigation at regular intervals
• communicating the outcome of any investigation as quickly as possible both to the complainant and to any individual against whom the complaint was made

• handling complaints promptly and efficiently and in confidence

• if the complainant takes their complaint to the media, then the HTA reserves the right to respond to any media enquiries

• process of investigation is open and transparent and details of the concerns raised will be shared with any individual who is the subject of the allegations wherever possible and appropriate

• complaints upheld provide an opportunity for the HTA to learn lessons and improve services

• providing every six months statistical and qualitative information to the Authority on the receipt, and outcome of complaints and lessons learned.

Procedure for handling complaints

Who can complain?

8. Any person or organisation directly affected or concerned by the alleged maladministration or poor service. A complaint may be made by a third party with the written authorisation of the complainant. The HTA will not investigate any complainant from an anonymous source.

Form of the complaint

9. Complaints may initially be made face to face, by letter, email or telephone and recorded on receipt. If the complaint cannot be resolved informally all complainants will be asked to submit full details of their allegations in writing to the Complaints Officer, so that the HTA can carry out an investigation of what occurred.

10. Correspondence should be sent by post or email to one of the addresses below:

By post: Complaints Officer
Human Tissue Authority
2nd Floor
151 Buckingham Palace Road
London SW1W 9SZ
By email: enquiries@hta.gov.uk

**Timing**

11. Complaints must be made within six months of the complainant becoming aware of the incident or issue giving rise to the allegation, to allow the HTA to carry out a viable investigation of the facts. However it is best if the complaint is made as soon as possible after the event.

12. If an investigation is required, the time taken to respond will vary depending on the urgency and complexity of the complaint. The HTA will acknowledge receipt of the complaint within three working days and respond to complaints within 20 working days of the written details of the complaint being received.

13. If the HTA is unable to respond within this time limit, for example because the allegations require more detailed investigation, the HTA will inform the complainant in writing and explain when it expects to make a decision.

14. In the event that the complainant is dissatisfied with the HTA’s decision and requests a review, this will be completed within 20 days from the date of this request.

**What outcome can a complainant expect?**

15. If a complaint is upheld, the HTA will:
   - give a written apology by acknowledging the failure, accepting responsibility for it, explaining clearly why the failure happened and expressing regret
   - where appropriate, take steps to put things right for the complainant and others who may have or would have been affected in a similar way
   - describe how the complainant can take the complaint forward if they are not satisfied with the HTA’s decision.

16. If a complaint is not upheld, the HTA will:
   - provide its decision in writing
   - explain how it came to its decision
   - describe how the complainant can take the complaint forward if they are not
satisfied with the HTA’s decision.

**What if the complainant is not satisfied with the HTA’s decision?**

17. If a complainant is not satisfied with the HTA’s decision and has new information to contribute to the investigation, the original investigator will consider the complaint in light of the new information.

18. If a complainant is not satisfied with the HTA’s decision and does not present any new information, then the complaint will be reviewed to ensure due process was followed and the correct decision reached. The review will include all correspondence and reference to this policy. The review will not entail a new investigation.

19. If after a review the complainant is still not satisfied with the decision then the complainant will be informed that they have the right to complain to the Ombudsman.

**Persistent complainants**

20. The HTA welcomes comments and complaints about its administration and service. However, the HTA will not tolerate abusive or threatening behaviour or language towards any member of staff.

21. Following complaint investigation and response, contact will be brought to a close. No further consideration will be given to the complaint unless new and relevant information is provided. If a complainant seeks to continue contact beyond this point, this will be limited to relevant explanation of the complaint response and advice about referral to the Ombudsman.

22. Further engagement by the HTA may inappropriately raise expectations of the likely outcome of continued contact. This may not be helpful to the complainant, or a reasonable or proportionate use of staff time and contact will be courteously brought to a close as quickly as possible.

23. In rare circumstances, the HTA may conclude that continued contact with a complainant has become ‘unreasonably persistent’. The following situations may fall within this definition:

- any contact that is continued without purpose after a full response has been provided; and it has been made clear that the HTA has nothing further to add to what has been said previously and the complainant has been advised to seek a referral to the Ombudsman
• where a complainant’s personal conduct (either in written contacts, telephone conversations or face to face meetings) towards HTA staff becomes abusive or unacceptable in tone or content.

24. In these circumstances, the decision to deem continued contact as unreasonably persistent will be made by the relevant Director (or where appropriate, the Chief Executive). Continued contact will be brought to a close by letter explaining the position and advising what action will be taken on receipt of further correspondence or contact from the complainant. In general, correspondence will be filed without reply. If there is continued contact by telephone, team members will be authorised to bring conversations to an end by explaining that the case has been closed and, if necessary, by terminating the call.

Monitoring and recording

25. All complaints will be centrally managed by the Chief Executive Officer’s Directorate, From December 2012; all complaints will be recorded in CRM as cases and captured on the complaints login impact. This knowledge will be used to ensure that maladministration or inappropriate conduct is not repeated. It will also be used to improve the HTA’s services.

26. Complaints about the HTA will be monitored regularly by the Senior Management Team and a report submitted to the Authority every six months.

Review

27. This policy will be reviewed annually.

Revision history

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Other related policies

Policy for handling allegations about licensed or unlicensed establishments

Policy for handling concerns from a whistleblower about licensed or unlicensed establishments
## Summary of process

### Indication of dissatisfaction

HTA staff or Member who receives an indication that a person is unhappy with the level of service provided, will try to resolve the complainant's concerns informally and as quickly as possible. The respondent will record the complaint in the Enquiries log. The Complaints Officer will be informed of complaint and attempt at resolution.

### Concerns resolved

- **Agrees with decision**
- **Disagrees with decision, has new information**

### Concerns unresolved

- **Complainant asked to put allegations in writing**

### Complaint received

When a formal written complaint is received, it is immediately forwarded to the Complaints Officer.

### Register, Acknowledge, Classify and Assign the complaint

The Complaints Officer registers the complaint in the Complaints log, acknowledges the complaint in writing within 3 working days, classifies what type of complaint it is, and assigns the complaint to the relevant team to investigate.

### Classify

| Policy for handling allegations about licensed or unlicensed establishments |
| Policy for handling concerns from a whistleblower about licensed or unlicensed establishments |
| Policy for handling complaints about maladministration or inappropriate conduct |

### Assign

- **Complaint is about:**
  - Chair - Member nominated by CE to investigate
  - Member - Chair to investigate
  - CE - Chair to investigate
  - HTA staff - Line Manager to investigate

### Investigate

Following the Ombudsman's Principles of Good Complaint Handling and Principles for Remedy.

### Communicate

Investigator will communicate the decision to the complainant and send a copy to Complaints Officer.

### Review

- **Complaint is about:**
  - Chair - different Member nominated by CE to review
  - Member - CE to review
  - CE - Member nominated by Chair to review
  - Director - Chair to review
  - HTA staff - relevant Director to review

### Procedure

Follow the procedure for handling allegations about licensed or unlicensed establishments.

### Communicate

Reviewer will communicate the decision to the complainant and Complaints Officer.

### Disagrees with decision

- **Recommend appeal to the Ombudsman**
appears to be a low spend for such a vital issue. As noted in previous HTA response documents on this matter, a new group of people will be impacted by the system year-on-year and while steps should have been taken during the implementation and launch phases to raise general awareness, campaigns will be required every year.

51. The HTA also questions whether an overall communications spend of £2.9m over ten years is adequate for such a significant legislative and operational change on a sensitive and complex issue.

The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation)

52. The HTA is not in a position to comment on the appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation.
Areas for further consideration

53. The HTA would highlight the following three areas as those which require further consideration and development, and which will be key to the effective implementation and operation of the proposed system.

Communications

54. The commitment made in the Explanatory Memorandum to an effective and sustained communications campaign is noted by the HTA. Communication will be vital in ensuring that every person living in Wales and the bordering counties is aware of the proposed system and how it will affect them. In order for the individual’s decision to remain paramount they must be aware of the action they are required to take, if any, to make their views known.

55. Communication with all Welsh residents and those living in the border counties will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English or Welsh, and also those living in deprived areas.

56. It will be important to develop a communications plan which ensures people who move to Wales are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, record their wishes.

57. The HTA considers that the planned communication with every Welsh resident six months prior to their eighteenth birthday will be important to ensure that there is time for these young people to make an active decision prior to deemed consent applying to them.

58. Any risk of a particular group or groups of Welsh residents being left behind on this matter due to poor communication must be actively addressed by the Welsh Government. Without an effective, comprehensive, targeted and continued communications campaign the proposed system cannot be said to hold the decision of the individual in life as a core principle. Indeed, without proper communication an individual may not be in receipt of the information they require to know what their silence on the matter of organ donation after their death will be considered to mean.
59. In previous responses to the Welsh Government’s consultations on an opt-out system for organ donation, the HTA has stressed the importance of a continuous communications campaign. Such a campaign will be critical in ensuring that every Welsh person is aware of whether or not the system affects them, and what action they need to take. If the focus on this continuous communications campaign is lost then there is a significant risk that people will not be properly informed, leading to the whole system being undermined.

60. The HTA is working with the Welsh Government to provide input on the communications activity for the proposed system.

Cross-border issues

61. The HTA believes that there is still work to be done on the cross-border issues which arise from the proposed system.

62. The introduction of a register for Welsh residents which records both wishes to donate, and wishes not to donate, would mean that there would be two different registers operating across the UK. In Wales it is envisaged that an individual will be able to record a yes to all organs, a yes to some organs, or an outright no. In the rest of the UK an individual will be able to record a yes to all organs, or a yes to some organs, they will not be able to register a no.

63. Operationally this poses challenges as under the HT Act it is the wishes of the individual immediately before they died which are held as primary, and therefore if these wishes are recorded on the Welsh register they should be acted on, no matter where the individual dies. This means that for Welsh residents who die outside Wales, the SNOD will be required to check any Welsh register which exists and act on the recorded wishes, if there are any. In fact, it would be prudent that any Welsh register is checked for every donor, as it may not be clear if they had ever been resident in Wales, and by checking both registers the risk that the “wrong” information is relied upon is limited. Therefore all SNODs must have access to any Welsh register and the Organ Donor Register and be in a position to easily establish whether a person is on either or both registers, and which record is most recent. This information will need to be quickly ascertained, most often in the middle of the night, and its accuracy must be guaranteed.

64. If individuals are able to record their wishes on the new Welsh register prior to implementation of the opt-out system, then this recording will in effect form the last recorded wishes of the individual, it is vital that these are made available to SNODS in order to ensure compliance with the HT Act.
Post implementation review

65. The consultation document commits to a thorough and on-going post implementation review and the HTA suggests that this seeks to highlight both successes and challenges. The HTA notes that both the Scottish Government and Northern Ireland Assembly\(^2\) have expressed interest in the Welsh Government’s proposals, and as such the post implementation review may form part of the basis of policy decisions in other parts of the UK. This unique opportunity to share the experience of one country of the UK with others should not be lost, and investigation of the true outcomes for all involved from donor families, to recipients and clinical staff will be key to the wider understanding of how such a system operates.

Conclusion

66. The HTA has been involved, to varying degrees over the past two years, in the development of the Welsh Government’s proposals which have resulted in the Bill which is the focus of this consultation.

67. The HTA is aware of the wide-range of views which exist on this matter, and as a statutory regulator has sought to provide advice and guidance on matters within remit and those areas in which the organisation has gained experience during the past eight years.

68. As detailed above, there are parts of the Bill which the HTA believes require further consideration and exploration.

69. However, it is those areas which are not specified in the Bill, for example the introduction of a Welsh register of people’s wishes, the communications strategy and post-implementation review where assurances are needed to give confidence to all involved in the proposal.

70. The HTA has welcomed and continues to welcome the Welsh Government’s collaborative approach on this issue, and believes that such an approach will go someway to delivering a successful outcome.
Governance – Decision-making Framework

Purpose of paper

1. To provide the Authority with an update on implementation of the recommendations from the internal audit relating to the HTA’s Decision-making Framework. The internal audit was undertaken by Grant Thornton in October 2012.

Action

2. The Authority is asked to note the progress on audit recommendations set out in paragraphs 9 and 10.

3. The Authority is asked to approve the proposed amendments to the “Schedule of delegation of powers to the Chief Executive, officers and committees” described in paragraphs 11 and 12 and Annex A.

Decision-making process to date

4. The Senior Management Team (SMT) agreed the findings of the audit in correspondence with Grant Thornton and the Audit Committee accepted the recommendations at its meeting on 14 November 2012.

5. SMT approved the proposals set out in this paper at its meeting on 10 January 2013.

Background

6. As part of the internal audit plan for 2012/13, the HTA commissioned Grant Thornton to undertake a review of its decision-making arrangements with a
view to identifying where these may need to be improved, and to provide evidence for the effective design of governance arrangements as part of any transfer of functions.

7. The audit found that the HTA has a robust, effective and transparent approach to making decisions that was appropriate and proportionate to its size and gave a green rating for the effectiveness of both the design and operation of the decision-making arrangements.

8. The audit also identified three low risk issues on which it made recommendations for action:

   i. All Authority papers, from January 2013 onwards, should include, where relevant, a clear description of the decision-making process to date and the status of the paper in terms of the overall decision-making process.

   ii. The précis of key documents (to include reference to decision-making procedures as appropriate) to be shared with all Members and SMT by 1 December 2012 and discussed at the January 2013 Authority meeting.

   iii. To complete the Decision-making Framework, informed, as appropriate, by the feedback in the audit report.

**Progress on audit recommendations**

9. Recommendation (i) has now been implemented from the January 2013 Authority meeting onwards. Members are asked to note this change.

10. The draft Decision-making Framework is attached in Annex A. The diagram at Annex B aims to discharge audit recommendation (ii). It sets out the groups within the HTA which contribute to decision making, and lists the documents which describe the remit and operation of each of these groups. Copies of any of these documents can be supplied to Authority Members on request.

11. The draft Decision-making Framework, when approved by SMT, will discharge recommendation (iii). The Framework will be completed by the end of the 2012/13 business year. This is contingent on the Executive completing its review of the HTA’s standard operating procedures.

12. As part of the development of the Framework, a number of amendments have been proposed to the “Schedule of delegation of powers to the Chief Executive, officers and committees”. This Schedule is an annex to the HTA standing order. The proposed amendments are shown in track changes on pages 7 and 8 below. The Authority is asked to approve these amendments.
Draft Human Tissue Authority (HTA) Decision-making Framework

In carrying out its functions, the Authority must, so far as relevant, have regard to the principles of best regulatory practice (including the principles under which regulatory activities should be transparent, accountable, proportionate, consistent and targeted only at cases in which action is needed). Human Tissue Act 2004, s.38 (2)

1. Description

1.1 In carrying out its statutory responsibilities, the HTA is required to make decisions on a wide variety of issues on a daily basis. To ensure that the HTA is transparent, accountable, proportionate, consistent, and targets its regulatory activity only at cases in which action is needed, a framework is required to assist the Authority in its decision making and to provide a standard against which the decisions taken can be judged.

2. Purpose

2.1 The purpose of this document is to set out:

- the scope of decisions which need to be controlled within the framework;
- the delegation scheme for decision making, to ensure that decisions in the HTA are taken in line with statutory requirements, and at the right level of seniority;
- the principles which underpin decisions covered by the framework.

3. Background

3.1 The Human Tissue Act 2004 (the Act) sets out the legal framework for the storage and use of human organs and tissue from the living and for the removal, storage and use of human organs and tissue from the deceased. The Act covers England, Wales and Northern Ireland. There is separate legislation in Scotland, the Human Tissue (Scotland) Act 2006. The HTA is the UK Competent Authority for the EU Tissue and Cells Directives - European laws that have been implemented in the UK via the Quality and Safety Regulations, and the EU Organ Donation Directive implemented in the UK via the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

3.2 Responsibility for superintending the Human Tissue Act rests with the Authority (the Chair and Authority Members) [s.15(c)]. The Authority is
allowed to appoint such staff as it sees fit [Schedule 2(11)] and may delegate any of its functions to any member of staff [Schedule 2(21)(b)].

3.3 The Act and associated regulations preclude the delegation of certain decisions (for example in relation to reconsiderations of licensing decisions) and in other circumstances the Authority has taken a decision to retain decision making responsibility as a matter of policy (for example, certain living donation cases).

3.3 The Standing Orders of the Authority set out the delegation of functions to the Chief Executive (see Annex A).

4. **Scope of decisions controlled within the framework**

4.1 This framework covers the following *decision categories*:

i. Decisions relating to the initial licensing of establishments

ii. Post inspection decision making

iii. Enforcement decisions (significant regulatory activity)

iv. Living organ donation decisions

v. Decisions relating to redress for those affected by our actions

vi. Decisions on action following receipt of information from outside the HTA

vii. Decisions on referral to the police

viii. Decisions on interpretation of our legal remit (policy decisions)

ix. Other decisions of strategic significance as defined in the Crisis Management Plan. That is to say, any other decision where HTA action; failure to act; or acting on the receipt of information received:

- could pose a risk to life, the public interest or public protection.
- could have a major detrimental impact on the integrity of the HTA as a regulator.
- could result in serious criticism or loss of faith – directly or indirectly – in us by our key stakeholders, including the Department of Health or other government departments, the public or the sectors that we regulate.

4.2 While this framework sets out the principles which should underpin HTA decision making, it does not provide a ‘how to’ guide for making decisions in every circumstance. More detailed guidance notes exist to assist delegated decision makers in coming to a view about the correct course of action in each particular decision class. (Directors in the relevant business areas are responsible for ensuring that these are in place and subject to regular review).
4.3 In a similar vein, this framework does not set out the process by which
decisions are made, but does mandate the need for standard operating
procedures which describe the decision making processes to be followed in
each decision category. Again, Directors in the relevant business area have
the responsibility to ensure that these are in place.

5. Delegation scheme for decision making

5.1 In order to function, the Authority must delegate decision making to the
Executive. The scheme of delegation ensures that decisions are taken at the
appropriate level of accountability relative to the likely risks associated with
the decision.

5.2 Delegation in the HTA comes from the top down. Directors are responsible for
putting in place mechanisms to assure the quality of decisions which are
delegated within their Directorates.

5.3 All delegated decision makers also have a responsibility for ensuring that
their decisions are consistent with this policy and any local guidance relating
to the decision. Delegated decision makers also have a duty to ensure that
where they have any doubt whether or not decision making is within their
remit, then this would be discussed with their line manager in the first
instance.

5.4 The delegation scheme is attached at Annex B.

6. Principles which guide decision making covered by this framework

6.1 It is neither possible, nor desirable, to set out what decision should be made
in every circumstance. The range of decisions to be made, and the
complexity of the information on which a decision will be based, limit the
scope for introducing clear cut decision rules. It is, however, possible to set
out the principles which should be applied when making a decision so that
there is consistency in how decisions are reached.

6.2 Decision making should take account of these principles and should be
reflected in more detailed guidance which supports decision making for
particular classes of decision.

6.3 Law – we must have the legal powers to make the decision and our decision
making processes should be lawful.
6.4 **Better regulation** – this framework should be accounted for in our decisions. That is to say we should be accountable for our decisions and they should be transparent, consistent, proportionate and targeted.

6.5 **Good practice** - decisions should be taken in line with our policies, procedures and guidance. They should be based on adequate evidence and properly documented.

6.6 **Strategic focus** – decisions should be consistent with or contribute towards the delivery of our strategic aims and high level business objectives. At the highest level, the decision should contribute to the safe and ethical use of human tissue, with proper consent.

6.7 **Risk awareness** – decisions should be appropriately risk-assessed. This should cover:
- an assessment of the risks associated with a departure from the standards we expect of our stakeholders
- an assessment of the risks associated with the decision we make, including their impact on those immediately affected and their stakeholders.

7. **Further implications**

7.1 Access to necessary legal advice needs to be built into decision making processes.

7.2 Appropriate risk assessment tools need to be developed to guide decision making.

7.3 Arrangements for record keeping need to factored in to processes.

**Revision history**

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Decision Making Framework Annex A – Standing Orders Extract

Schedule of delegation of powers to the Chief Executive, officers and committees

Framework of delegation to the Chief Executive and officers reporting to the Authority on that delegation

1. The Chief Executive will prepare each year a three year strategic plan and annual business plan for approval by the Authority and agreement between the Authority and the Department. Alongside these plans, the Chief Executive will prepare a budget for the financial year showing proposed expenditure under main headings and against main activities.

2. Once approved by the Authority, the Chief Executive will be responsible for putting these plans into effect and has authority to take such decisions as are necessary relating to the employment of staff and the engagement of financial or other services.

3. The Authority may agree policies in relation to its statutory functions and the Chief Executive will be responsible for ensuring that those policies are followed. The Chief Executive may propose to the Authority policies in relation to any of its functions and once approved by the Authority, shall act in accordance with those policies.

4. The Chief Executive must act within any overall limits and conditions set in relation to the Authority’s expenditure as informed to the Authority by the Department and may:
   a. approve and certify expenditure;
   b. authorise payments and accept receipts;
   c. negotiate, organise and review banking arrangements;
   d. vire money between budgets;
   e. make any arrangements necessary relating to the employment of staff, their terms, conditions and pay; and
   f. Sub-delegate his/her powers to members of the Authority’s staff.

5. These delegated authorities shall be subject to the limits set by the Department of Health effective from 1 April 2009.

6. The Chief Executive will report to the Authority and advise the Authority in a timely manner of all material matters currently or prospectively affecting the HTA and its performance.

7. In particular, the Chief Executive will report each quarter to the Authority on the achievement of key targets set out in the business plan and on the Authority’s expenditure and income against its budget.
9. The Chief Executive will report to the Authority any significant proposal to vary the staffing structure of the HTA.

10. The Chief Executive or other officer authorised by him/her is authorised to apply and authenticate by his or her signature the seal of the Authority.

11. The Authority delegates the power to grant, revoke, vary and suspend licences issued under the Authority’s remit to the Chief Executive, who may then delegate decisions to members of staff (usually from the Regulation Directorate).

12. This delegation extends to the hearing of representations from applicants against decisions made by members of staff.

13. The Authority delegates to the Chief Executive the power to assess and make decisions on applications for living organ donation except those which are retained by the Authority as a result of Regulations and those which it has decided to retain as a matter of policy.

14. Delegation by the Chief Executive is set out in the Onward Delegation Scheme.

Framework of delegation to committees reporting to the Authority on that delegation

15. A committee can take decisions on matters contained within its terms of reference unless the matter is reserved for decision by the full Authority on the recommendation of that committee.
## Decision Making Framework Annex B - Onward Delegation Scheme

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<td>Grant of a licence</td>
<td>Regulation Manager</td>
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<td>Varying a licence</td>
<td>Regulation Manager or Officer</td>
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<td>Extending a licence</td>
<td>Regulation Manager</td>
</tr>
<tr>
<td>Post-inspection decision-making</td>
<td>Major and minor shortfalls</td>
<td>Regulation Manager with a Head of Regulation</td>
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<td>Enforcement decisions (significant regulatory activity)</td>
<td>Critical shortfalls or collection of major shortfalls</td>
<td>Regulatory Decision Meeting (Director or Head of Regulation)</td>
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<td></td>
<td>some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.</td>
<td>Regulatory Decision Meeting (Director or Head of Regulation)</td>
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<td>Regulatory Decision Meeting (Director or Head of Regulation)</td>
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<td>a notice of suspension of licensable activities</td>
<td>Regulatory Decision Meeting (Director or Head of Regulation)</td>
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<td>a notice of proposal being issued to revoke the licence</td>
<td>Regulatory Decision Meeting (Director or Head of Regulation)</td>
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<td>Decisions on representations made following a decision to place conditions on a licence or suspend a licence</td>
<td>Panel of three members of staff (must not include the original inspectors, decision maker or anyone else involved in the original decision. The Chair must be a Head of Regulation or Director)</td>
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<td>Issuing general directions</td>
<td>Director or Head of Regulation</td>
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<td>Living organ donation decisions</td>
<td>Approval of non-panel cases</td>
<td>Officers</td>
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<td>Refusal of non-panel cases</td>
<td>Regulatory Decision Meeting (Director)</td>
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<td>Appeals</td>
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<td>by our actions</td>
<td>Post inspection decisions (where an inspection has been undertaken as a result of the information received)</td>
<td>Regulation Manager with a Head of Regulation</td>
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<td>Decisions on the interpretation of our legal remit (policy decisions)</td>
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HTA (06-13) Governance - Decision Making Framework - Annex B

Groups

Authority Groups

Authority

Decision making

Standing committees

Audit Committee

Delegated decision making

Remuneration Committee

Delegated decision making

Panels convened for specific purposes

Transplant Panel

Decision making

Reconsiderations panel

Decision making

Appeals Committee

Decision making

Authority/Executive Groups

PRAG

Advisory

Comms Members’ Group

Advisory

Executive

Histopathology Working Group

Advisory

Transplant Working Group

Advisory

Authority/Executive Groups

Member groups

PRAG Terms of reference

CMG Terms of reference (TBC)

Working groups

HTAMG Terms of reference

Regulatory decision meetings

Representations meeting

Decision making groups

Case review meetings

Regulatory decision meetings

Representations panel

Regulations Directorate

SMT Terms of reference

HTA Policy for managing and referring potential criminal breaches of Human Tissue legislation (Draft)

S&Q Directorate

HTAMG Terms of reference

Decision making

Licensing decisions

Regulatory decisions

Individual decision making

Living transplant approvals

APPROVED REG-SOP-026 Regulatory Decision Making

SOP-LDAT 040 LOD Case Review Meeting (draft)

APPROVED REG-SOP-014 Representations

APPROVED REG-SOP-003 Evaluating new Licence Applications

APPROVED REG-SOP-026 Regulatory Decision Making

SOP-001 Assessment process for living donor transplant cases 2012 (Draft)
Financial report – December 2012

Introduction

1. This paper provides an update of the Human Tissue Authority’s (HTA) financial position as at 31 December 2012, nine months into the business year.

2. The report provides commentary on the following areas:
   
   - financial position to 31 December 2012
   - forecast outturn for the year
   - other performance indicators
   - financial risks

Action

3. The Authority is asked to note the financial position as at 31 December 2012.

Decision-making process to date

4. This paper is for information and the contents have not required any decisions to be made.

Overview of financial position at 31 December 2012

5. Annex A shows the summarised financial position for the year to 31 December 2012. At that date, there was an under-spend on revenue expenditure of £182k and £968k less income in total than anticipated. Together these resulted in a variance of £786k more than expected before rebates and internal adjustments.
6. Exceptional items have been added to the reports. The first is a credit of licence fee relating to 2011/12 that was not required as the licence was revoked. Secondly, there has also been a release of accruals from the 2011/12 financial year. These were no longer needed and are shown here to ensure the accounts are not distorted. The effect of the exceptional items takes the overall variance to £757k.

**Income – variances to 31 December 2012**


8. Less Grant-in-aid (GIA) is being drawn down as the mechanism for using £500k reserves (see paragraph 16). The balance of GIA of £145k will be drawn down by the end of this business year.

9. There is less licence fee income than expected, particularly within the Tissue for Patient Treatment (Human Application) sector (£61k) and the Post Mortem sector (£157k). The shortfall of EU ODD income (£339k) arises due to the fee subsidy and the HTA covering the cost of regulating this sector from its reserves.

10. Other income includes a small recharge (£13k) to the Devolved Assemblies (Northern Ireland and Scotland) for their share of the costs of implementing the EUODD.

11. Also within other income is EU funding for the SoHo V&S project. This was not included in the budget initially and expenditure is now shown following audit advice. Costs, which consist mainly of staff time and some travel expenses, are included within the normal costs of operation but kept together within the project cost code.

12. By the end of the financial year we expect further SoHo V&S costs relating to the conference organised by the HTA. Travel and accommodation costs will be offset by the final tranche of funding and reflected in the February or March 2013 accounts.

**Expenditure – variances to 31 December 2012**

13. Annex C shows expenditure as at 31 December 2012 for staff and non-staff costs. There is an overall under-spend of £212k.

14. The under-spend within staff costs of £292k is the result of vacancies which have arisen and the adjustments to remove staff costs relating to EU ODD work and SoHo V&S (which are recorded as project costs within non staff costs).
15. There is an over-spend of £110k on non-staff costs. This is due to the adjustments referred to above for staff and other costs relating to EU ODD (£236k which covers all directorates) and is partially offset by other under-spends, most notably Legal and Professional services (£58k).

<table>
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<tbody>
<tr>
<td>Staff costs</td>
<td>292,448</td>
<td>Vacant posts and project work.</td>
</tr>
<tr>
<td>Non staff costs</td>
<td>(110,238)</td>
<td>This variance is analysed in greater detail in the lines below.</td>
</tr>
<tr>
<td>Conferences &amp; Project costs</td>
<td>(230,156)</td>
<td>Costs pertaining to SoHo V&amp;S and ODD now included.</td>
</tr>
<tr>
<td>Legal &amp; Professional</td>
<td>55,749</td>
<td>Under-spend on Legal (53k) as less external advice has been required. Small underspend on Internal and Insurance costs.</td>
</tr>
<tr>
<td>Consultancy</td>
<td>12,000</td>
<td>Budget profiling. No spend to date.</td>
</tr>
<tr>
<td>Accommodation</td>
<td>13,039</td>
<td>Underspend on Building Services.</td>
</tr>
<tr>
<td>Non Cash costs</td>
<td>(26,038)</td>
<td>Bad debts written off (£32k) offset by understspend on External Audit cost.</td>
</tr>
<tr>
<td>Capital charges</td>
<td>43,327</td>
<td>Amortisation charges lower than budgeted.</td>
</tr>
<tr>
<td>Other variances</td>
<td>21,841</td>
<td>Mainly due to variances within Travel and Subsistence, Other Costs and IT &amp; Telecommunications.</td>
</tr>
</tbody>
</table>

1 () denotes an over-spend

16. **Annex D** provides an analysis of expenditure by Directorate. All Directorates are under-spending, for the reasons reported above. There is also a contingency budget, held in Resources, for projects and any unexpected pieces of work, which has been not utilised as yet.

**Forecast outturn**

17. As of the end of December (nine months into the business year), we are forecasting an overall year end over-spend against budget of £620k. This forecast assumes that we will spend some of the contingency budget – if this is not the case, the over-spend would reduce by £56k.

18. An over-spend is to be expected because of the use of HTA reserves on the EU ODD sector (c£340k) following DH’s agreement to subsidise fees and the repayment of some reserves to DH (£500k) via a reduction in Revenue GIA. The reduction in fee income from other sectors is mainly offset by expected reduced spend.
19. Uncertainties about some areas of spend may alter the forecast but it not expected to be too far from that stated. Further review of spend during Q4 will give a final indication of our expected outturn.

20. The expenditure forecast now includes future non staff costs pertaining to EU ODD implementation but not costs for the SoHo V&S conference project. Final costs are expected to arise for the SoHo project towards the end of February 2013 and these will be reimbursed to the HTA from Europe.

Other key performance indicators

Reserves

21. Total reserves at the end of December are £3.8m. Our cash balance is £2.7m.

Cashflow

22. The cashflow continues to be monitored against the forecast that was prepared at the beginning of the year. We expect a year end cash balance of £1.8m, compared to our forecast at the beginning of the year of £1.4m. The position is healthy at present. The differences from the forecast arise from the reduction in total expenses and the increase in expected licence fee income.

Debtors

23. As at 31 December our licence fee gross debtor balance was £35k (12 establishments), Gross debtors are 77% less than they were at this time last year.

24. Of the fees that are outstanding, 4 relate to the 2011/12 business year and 2 relate to early 2012/13. 58% is due from NHS bodies and 42% from bodies external to government.

25. All of the above debtors are being pursued by our Head of Legal. 2 of the establishments are NHS and the remainder are from the private and third sector.

26. Of the 6 establishments from the September billing round, two have paid in January 2013, one is paying in instalments and payment is expected from a further one. The other two are being pursued.

Prompt payment

27. For the nine months ended 31 December, 89% (December only, 88%) of invoices were paid within 5 days. Average payment time was 2.30 days. There has been a slight deterioration in December, due to fewer payruns over the Christmas period, but performance is still satisfactory.
## Financial risks

<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 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 then need to be managed to reflect income or unavoidable costs recovered through licence fees.</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>
Human Tissue Authority

Summary - Income & Expenditure

For the Nine Months Ending 31 December 2012

<table>
<thead>
<tr>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
</tr>
<tr>
<td>Income</td>
<td>(£)</td>
</tr>
<tr>
<td>Less: Expenditure</td>
<td>3,168,360</td>
</tr>
<tr>
<td>Gross (surplus)/deficit of income over expenditure</td>
<td>(330,300)</td>
</tr>
<tr>
<td>Exceptional items</td>
<td></td>
</tr>
<tr>
<td>Internal adjustments</td>
<td>(28,067)</td>
</tr>
<tr>
<td>Rebate(s)</td>
<td>(1,369)</td>
</tr>
<tr>
<td>Total Exceptional Items</td>
<td>(29,436)</td>
</tr>
<tr>
<td>Net (surplus)/deficit of income over expenditure</td>
<td>(359,736)</td>
</tr>
</tbody>
</table>
## Grant In Aid

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals (£)</td>
<td>Budget (£)</td>
</tr>
<tr>
<td>GIA</td>
<td>214,750</td>
<td>643,950</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>214,750</td>
<td>643,950</td>
</tr>
</tbody>
</table>

## Licence Fees

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals (£)</td>
<td>Budget (£)</td>
</tr>
<tr>
<td>Anatomy</td>
<td>93,100</td>
<td>93,100</td>
</tr>
<tr>
<td>Post Mortem</td>
<td>1,214,074</td>
<td>1,370,904</td>
</tr>
<tr>
<td>Public Display</td>
<td>15,800</td>
<td>21,200</td>
</tr>
<tr>
<td>Research</td>
<td>547,200</td>
<td>573,300</td>
</tr>
<tr>
<td>Human application</td>
<td>1,263,969</td>
<td>1,325,100</td>
</tr>
<tr>
<td>Licence Fees - EU ODD</td>
<td>0</td>
<td>339,489</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>3,134,144</td>
<td>3,723,093</td>
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</tbody>
</table>

## Other

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals (£)</td>
<td>Budget (£)</td>
</tr>
<tr>
<td>Other income</td>
<td>49,545</td>
<td>0</td>
</tr>
<tr>
<td>Scottish &amp; N. Ireland Execs. &amp; Welsh Assembly</td>
<td>100,221</td>
<td>100,221</td>
</tr>
<tr>
<td>Sub-Total</td>
<td>149,766</td>
<td>100,221</td>
</tr>
</tbody>
</table>

## Total Income

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals (£)</td>
<td>Budget (£)</td>
</tr>
<tr>
<td>Total Income</td>
<td>3,498,659</td>
<td>4,467,264</td>
</tr>
</tbody>
</table>
## EXPENDITURE SUMMARY

<table>
<thead>
<tr>
<th></th>
<th>Year to Date</th>
<th>FORECAST</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
</tr>
<tr>
<td></td>
<td>£</td>
<td>£</td>
</tr>
<tr>
<td><strong>Staff Costs</strong></td>
<td>1,731,086</td>
<td>2,023,534</td>
</tr>
<tr>
<td><strong>Non Staff Costs</strong></td>
<td>1,437,274</td>
<td>1,327,036</td>
</tr>
<tr>
<td><strong>Gross Costs before Exceptional Items</strong></td>
<td>3,168,360</td>
<td>3,350,570</td>
</tr>
<tr>
<td><strong>Exceptional items</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal adjustments</td>
<td>(28,067)</td>
<td>0</td>
</tr>
<tr>
<td>Rebate(s)</td>
<td>(1,369)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Exceptional Items</strong></td>
<td>(29,436)</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total Expenditure</strong></td>
<td>3,138,923</td>
<td>3,350,570</td>
</tr>
</tbody>
</table>

14/01/13
10:57 AM
<table>
<thead>
<tr>
<th>Department</th>
<th>Year to Date</th>
<th></th>
<th>Variance</th>
<th>Outturn</th>
<th>Budget</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Actuals</td>
<td>Budget</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulation</td>
<td>1,090,077</td>
<td>1,076,368</td>
<td>13,709</td>
<td>1.27%</td>
<td>1,445,829</td>
<td>1,462,557</td>
</tr>
<tr>
<td>Strategy and Quality</td>
<td>226,176</td>
<td>237,264</td>
<td>(11,088)</td>
<td>-4.67%</td>
<td>302,417</td>
<td>316,919</td>
</tr>
<tr>
<td>HTA Board</td>
<td>131,388</td>
<td>131,657</td>
<td>(270)</td>
<td>-0.20%</td>
<td>171,299</td>
<td>173,543</td>
</tr>
<tr>
<td>Resources</td>
<td>1,217,486</td>
<td>1,354,664</td>
<td>(137,179)</td>
<td>-10.13%</td>
<td>1,699,133</td>
<td>1,966,158</td>
</tr>
<tr>
<td>Chief Executive's Office</td>
<td>334,381</td>
<td>364,670</td>
<td>(30,289)</td>
<td>-8.31%</td>
<td>457,859</td>
<td>514,827</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td><strong>3,168,360</strong></td>
<td><strong>3,350,570</strong></td>
<td><strong>(182,210)</strong></td>
<td><strong>-5.44%</strong></td>
<td><strong>4,291,839</strong></td>
<td><strong>4,681,914</strong></td>
</tr>
<tr>
<td><strong>Exceptional adjustments</strong></td>
<td><strong>(28,067)</strong></td>
<td><strong>0</strong></td>
<td><strong>(28,067)</strong></td>
<td><strong>(28,067)</strong></td>
<td><strong>0</strong></td>
<td><strong>(28,067)</strong></td>
</tr>
<tr>
<td><strong>2006-2010 Rebate</strong></td>
<td><strong>(1,369)</strong></td>
<td><strong>0</strong></td>
<td><strong>(1,369)</strong></td>
<td><strong>(1,369)</strong></td>
<td><strong>0</strong></td>
<td><strong>(1,369)</strong></td>
</tr>
<tr>
<td><strong>Total Directorate(s) Expenditure</strong></td>
<td><strong>3,138,923</strong></td>
<td><strong>3,350,570</strong></td>
<td><strong>(211,646)</strong></td>
<td><strong>-6.32%</strong></td>
<td><strong>4,262,403</strong></td>
<td><strong>4,681,914</strong></td>
</tr>
</tbody>
</table>
Authority Paper

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.

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 in January 2013. There were minimal 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 last significant change was to risk rating was in October 2012. The risk of inadequate relationship/stakeholder management reduced to green, following very positive feedback and responses to the Arm’s Length Bodies review consultation.

8. Since the last consideration of risk at an Authority meeting, the impact of the Welsh legislation to introduce an opt-out system for organ donation has been noted as a risk and we have added arrows to identify the trend of risks, even though their overall rating has not changed.

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

10. The Audit Committee will review risk management in more detail at their meeting on 7 February 2013.

Annex A – Strategic risk register, January update
Annex B – Log of changes to strategic risk register
Overview:
No significant changes from September. 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.

<table>
<thead>
<tr>
<th>Risk</th>
<th>February 2012</th>
<th>June 2012</th>
<th>November 2012</th>
<th>December 2012</th>
<th>January 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 about to go on maternity leave) and there is still uncertainty about pay and our future.</td>
</tr>
<tr>
<td>2 – Managing change</td>
<td></td>
<td></td>
<td></td>
<td>→ ↑</td>
<td></td>
<td>Although the pace of change has slowed and there is more acceptance about the changes, the HTA continues to live with uncertainty, pending the outcome of the ALB Review consultation. The potential proximity of the decision, and change likely due to the Welsh legislation, has caused an increase in the risk level.</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 care will be taken later in the year when reserves are likely to reduce.</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.</td>
</tr>
</tbody>
</table>

Risks are assessed by using the grid below.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Almost</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Minor</td>
<td></td>
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</tr>
<tr>
<td>3. Moderate</td>
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<td></td>
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<tr>
<td>4. Significant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Catastrophic</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ref</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>
</tr>
<tr>
<td>-----</td>
<td>------------</td>
<td>-------------------</td>
<td>-----------------------</td>
<td>-----------</td>
<td>-------------------------------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>1</td>
<td>Inability to carry out its statutory remit (strategic objective 1)</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 following publication of the ALB consultation document.</td>
<td>L</td>
<td>Ongoing</td>
<td>• Strategic plan and business plan review and implementation 4</td>
<td>• Review and implement recommendations from staff forum (AC lead) Ongoing 4</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>
</tr>
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</tr>
<tr>
<td>2</td>
<td>Failure to manage change</td>
<td>Alan Clamp</td>
<td>Underpins delivery of all strategic objectives and directly impacts on 3, 4 and 5</td>
<td>I</td>
<td>Ongoing</td>
<td>Corporate leadership by SMT and Heads</td>
</tr>
<tr>
<td></td>
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<td>L</td>
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</tr>
<tr>
<td>Ref</td>
<td>Risk</td>
<td>Cause and Effects</td>
<td>Inherent Risk Priority</td>
<td>Proximity</td>
<td>Existing Controls/Mitigations</td>
<td>Residual Risk Priority</td>
</tr>
<tr>
<td>-----</td>
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<td>-------------------</td>
<td>------------------------</td>
<td>-----------</td>
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</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) | Cause:  
- 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  
Effect:  
- Loss of public confidence  
- Reputational damage  
- Legal action against the HTA  
- Intervention by sponsor body  | I | Future, should event occur | 5 | 3 | Filled identified business-critical roles  
- Resource plan in place  
- Crisis management policy and guidance in place  
- Media handling policy and guidance in place to supplement media release and enquires SOPs  
- Crisis communications plan regularly reviewed  
- 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  
- Refreshed regulation training programme in place | 3 | 2 | Report to Authority about decision making(AMS) January 2013  
- Crisis management document to be updated following training, and communicated to all staff (SGr) (January 2013) |  |  | Same |

Risk owner: Shaun Griffin
<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>4</td>
<td>Insufficient financial resources (underpins delivery of all strategic objectives and directly impacts on 5)</td>
<td></td>
<td>4 4</td>
<td>2012/13 at earliest</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Same</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>
<td>Assured position</td>
</tr>
<tr>
<td>-----</td>
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</tr>
</tbody>
</table>
| 5   | Inadequate relationship/stakeholder management (strategic objective 2) | Shaun Griffin | - 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  
- ALB Review and proposal to move to CQC undermines regulatory status  
- Impact of EU Organ Donation Directive and new framework for living organ donation adversely affects relationship with the transplant community  
- Impact of organ donation proposals in Wales  
- Ineffective regulatory processes  
- Failure to act in a lawful manner  
- Joint working with other organisations (may impact adversely on HTA approach) | I L | Ongoing with potential peak following ALB decision | | | Ensure HTA’s expectations on Governance arrangements are made clear in our discussions following the ALB consultation (AC) Ongoing | Communications evaluation reports to Authority and Communications Members’ Group meetings quarterly, and meeting minutes  
Location of survey (stakeholder evaluation completed every 3 years and ad hoc surveys) | Same |

**Effect**
- Complaints to HTA and/or government  
- Poor regulatory compliance  
- Reputational damage  
- Reduction in public and professional confidence
## Log of changes to Strategic Risk Register – January 2013

<table>
<thead>
<tr>
<th>Risk</th>
<th>Column</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front sheet</td>
<td>January 2013</td>
<td>Added and November 2011 deleted.</td>
</tr>
<tr>
<td>Front sheet</td>
<td>Comments</td>
<td>Minor change to risk 2</td>
</tr>
<tr>
<td>1 – Inability to carry out statutory remit</td>
<td>Cause and effects</td>
<td>Concern about pay levels added</td>
</tr>
<tr>
<td>1 – Inability to carry out statutory remit</td>
<td>Actions to improve mitigation</td>
<td>Updated to reflect decision taken regarding Codes and action in January. New action added as shown.</td>
</tr>
<tr>
<td>2 – Failure to manage change</td>
<td>Existing controls</td>
<td>MoU added</td>
</tr>
<tr>
<td>2 – Failure to manage change</td>
<td>Actions to improve mitigation</td>
<td>Additional action as shown</td>
</tr>
<tr>
<td>5 – Inadequate stakeholder management</td>
<td>Actions to improve mitigation</td>
<td>Additional action shown</td>
</tr>
</tbody>
</table>
Authority paper

Date 22 January 2013  Paper reference HTA (09/13)
Agenda item 13  Author Allan Marriott-Smith

Strategic Performance Review – December 2012

Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during December. Members are asked to note the content of the report.

Action

2. The Authority is asked to note the content of the report.

Decision-making process to date

3. SMT 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 December.
Progress in December 2012

Regulation

5. KPI 1.2 [At least 77 inspections of Human Application (HA) establishments to take place during the business year, ensuring EU requirements are met] is red as a total of 75 HA inspections will have taken place by the end of this business year.

6. Voluntary revocation and the merging of licences have had an impact on the overall number of establishments and also the inspection figures. Of particular relevance, two existing (and previously inspected) establishments are merging to form one new establishment on new premises; we have therefore postponed the two planned inspections this business year in favour of an inspection at the new premises in the next business year. Although this means that the existing two establishments will miss their two-yearly re-inspection, they will merge to form a new entity soon and we felt it was proportionate and more efficient to rearrange for an inspection of the new establishment in early 2013/14.

7. We were not able to schedule replacement inspections as the information on the merger being received recently. The inspection scheduling team looked again at March 2013, the earliest realistic time to schedule any additional inspections due to the notice required, but we were already at full capacity (a total of 22 routine / themed inspections, and transplantation sector audits, are taking place). The limitations of this type of fixed indicator will be considered with regard to next year’s business plan monitoring.

8. All other KPIs currently reportable are green or within tolerance.

Strategy and Quality

9. All KPIs currently reportable are green or within tolerance.

Communications and Public Affairs

10. All KPIs currently reportable are green or within tolerance.

Resources

11. All KPIs currently reportable are green or within tolerance.
12. **The vacancy rate** (KPI 3.1) is green with an outturn of 2% against a target rate of 5%. There was one vacancy at the end of December 2012 for a Regulation Manager.

13. KPI 3.2 **relating to attrition** is green, 18% against a target of 18% for the rolling year January to December 2012. Eleanore Sheriffs left the HTA during December.
<table>
<thead>
<tr>
<th>Number</th>
<th>Code</th>
<th>Agreement type</th>
<th>Agreement objective</th>
<th>Indicator type</th>
<th>Performance indicators</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>A</td>
<td>Regs</td>
<td>To improve the efficiency and effectiveness of our regulatory activity and advice and guidance to licensed establishments</td>
<td>Strategic aim</td>
<td>At least 90% of completed applications to vary a licence are processed within 20 working days of receipt (reported quarterly)</td>
</tr>
<tr>
<td>1.2</td>
<td>B</td>
<td>Regs</td>
<td>To inspect establishments regulated under the Human Tissue Act, the Q+S Regs and the OT Regs</td>
<td>Strategic aim</td>
<td>At least 77 inspections of HA establishments to take place during the business year. Measure QTR 1 - JB - 14 HA inspections conducted in QTR 1. On track to meet target by end of business year. QTR 2 - JB - On course to meet target by the end of the business year. QTR 3 - AW - 45 completed and more selected. Measure: Grey Grey 14/77 Grey Grey 32/77 Grey Grey 45/77 Grey Grey 0%</td>
</tr>
<tr>
<td>1.3</td>
<td>C</td>
<td>Regs</td>
<td>To review Directorate products, processes and policies to ensure they are efficient, effective and within legal remit.</td>
<td>Strategic aim</td>
<td>At least 95% of enquiries are answered within 10 working days of receipt Measure: Grey Grey Green Grey Grey Green Grey Grey Green Grey Grey</td>
</tr>
<tr>
<td>1.4</td>
<td>D</td>
<td>Regs</td>
<td>To provide advice and guidance on regulatory requirements of the Organ Donor Directive</td>
<td>Strategic aim</td>
<td>At least 80% of responding establishments rate the overall inspection process as either 'good' or 'excellent' (reported quarterly) Measure: Grey Grey Green Grey Grey Green Grey Grey Grey Grey Grey</td>
</tr>
<tr>
<td>1.5</td>
<td>E</td>
<td>Regs</td>
<td>To inspect and receive written confirmation that comprehensive risk assessments to address major shortfalls are completed within agreed timescales.</td>
<td>Strategic aim</td>
<td>At least 90% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed within agreed timescales. Measure: Grey Grey Green Grey Grey Green Grey Grey Grey Grey Grey</td>
</tr>
<tr>
<td>1.6</td>
<td>F</td>
<td>S&amp;Q Measure</td>
<td>To review task completion and project implementation stage of the Living Donation Framework project.</td>
<td>Strategic aim</td>
<td>At least 95% of approval applications to donate a kidney are processed within 10 working days of receipt (reported quarterly). Measure: Red Amber Amber Amber Amber Green Green Green Green Green Green</td>
</tr>
<tr>
<td>1.7</td>
<td>G</td>
<td>S&amp;Q Measure</td>
<td>To review task completion and project implementation stage of the Living Donation Framework project.</td>
<td>Strategic aim</td>
<td>Proportion of non-panel cases turned around within 5 working days (measured monthly). Target: 98% Measure: Green Green Green Green Green Green Green Green Green Green Green</td>
</tr>
<tr>
<td>1.8</td>
<td>H</td>
<td>S&amp;Q Measure</td>
<td>To review task completion and project implementation stage of the Living Donation Framework project.</td>
<td>Strategic aim</td>
<td>Proportion of panel cases turned around within 10 working days (measured monthly). Target: 98% Measure: Green Green Green Green Green Green Green Green Green Green Green</td>
</tr>
<tr>
<td>1.9</td>
<td>I</td>
<td>S&amp;Q Measure</td>
<td>To review task completion and project implementation stage of the Living Donation Framework project.</td>
<td>Strategic aim</td>
<td>Online submission system delayed - all other aspects of project launched on 10 September as planned Measure: Green Green Green Green Green Green Green Green Green Green Green</td>
</tr>
<tr>
<td>1.10</td>
<td>J</td>
<td>S&amp;Q Measure</td>
<td>To undertake activity to implement the requirements of the Organ Donor Directive</td>
<td>Strategic aim</td>
<td>To undertake activity to implement the requirements of the Organ Donor Directive. Measure: Green Green Green Green Green Green Green Green Green Green Green</td>
</tr>
<tr>
<td>1.11</td>
<td>K</td>
<td>S&amp;Q Measure</td>
<td>To manage the living organ donation approvals process</td>
<td>Strategic aim</td>
<td>At least 90% of applications for living organ donation are processed within 10 working days (measured monthly). Target: 98% Measure: Green Green Green Green Green Green Green Green Green Green Green</td>
</tr>
</tbody>
</table>

**Comments**

- APR - IS - Parliamentary procedures may cause a delay to implementation. All internal processes are still on track to deliver full implementation by 27 August.
- MAY - IS - All internal processes are still on track to deliver full implementation by 27 August. However, the parliamentary process may yet create difficulties although the situation has stabilised since the last report.
- JUN - IS - The bids will remain order until all licence assessments have been completed and full licences issued by the end of December 2012. Currently, all work packages supporting this project are on track to deliver within the prescribed time frames of the project.
1. To ensure appropriate and effective relationships in our changing operational environment
   a. To maintain and build confidence, and communicate the need and purpose to the communities at the heart of our work
   b. To establish and maintain and maintain the principles and values of the organisation
   c. To manage the reputation of the HTA effectively

2. To manage internal and external audit evidence and to ensure that the audit process is fair, effective, consistent and timely
   a. To ensure internal and external audit evidence is fair, effective, consistent and timely
   b. To ensure that all aspects of the audit process are fair, effective, consistent and timely
   c. To ensure that all aspects of the audit process are fair, effective, consistent and timely

3. To have a skilled, motivated and dedicated team equipped to do the job in a challenging transitional period
   a. To further improve the HTA's working environment and culture to retain staff and uphold the HTA's standards and values
   b. To attract, motivate, retain and attract colleagues to deliver an excellent work
   c. To improve the quality of the HTA's communications and development

4. To ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the public
   a. To maintain governance arrangements which give appropriate oversight to matters within the HTA's legislative remit
   b. To maintain high quality management skills and expertise
   c. To manage the reputation of the HTA effectively

| KPI 2.1 | C&PA | Milestone | Evaluation and evidence of the effectiveness of HTA communications

| KPI 3.1 | CEO | Measure | To maintain and build confidence amongst professionals and the public in the regulation of the removal, storage and use of human tissue

| KPI 3.2 | CEO | Measure | To implement targeted retention initiatives Target rate of 18% for attrition rate measured monthly on a rolling annual basis.

| KPI 3.3 | CEO | Measure | Staff numbers for 2012/13 do not exceed 46 or spend does not exceed £4.7m (KPI)

| KPI 4.1 | C&PA | Measure | Recruitment and appointment of suitable professional staff in line with the HTA's legislative remit

| KPI 4.2 | Res | Measure | To deliver the efficiency plans for 2012/13

| KPI 4.3 | Res | Measure | To deliver an effective learning and development programme