

Fifty-First Meeting of the Human Tissue Authority

Date 27 September 2011
Time 10.30am – 1.00 pm
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 26 July 2011 HTA (43/11)
4. Matters arising
5. Chair's report Oral
6. ALB review and shared services update (I) HTA (44/11) CEO
7. Update on the implementation of the Organ Donation Directive (I) HTA (45/11) AC
8. Revision of the HTA's Codes of Practice (I) HTA (46/11) AMS
9. Report on the introduction of presumed consent in Wales (I) HTA (47/11) AMS
10. Framework for living organ donation assessment - update (I) HTA (48/11) AMS
11. Communications Strategy – update (I) HTA (49/11) SGr
12. Financial report August 2011 (I) HTA (50/11) SGa
13. Strategic performance review August 2011 (I) HTA (51/11) AMS
14. Any other business



Minutes of the fiftieth meeting of the Human Tissue Authority

Date 26 July 2011

Venue Wellcome Collection
183 Euston Road
London
NW1 2BE

Present

Members

Baroness Diana Warwick (Chair)
Professor Michael Banner
Mrs Jodi Berg
Mr Brian Coulter
Professor Susan Dilly
Mrs Pamela Goldberg
Mrs Suzanne McCarthy
Mr Keith Rigg
Ms Catharine Seddon

In attendance

Mr Craig Muir (Chief Executive)
Dr Alan Clamp (Director of Regulation)
Dr Shaun Griffin (Director of Communications and Public Affairs)
Mrs Sue Martin (Director of Resources)
Mr Allan Marriott-Smith (Director of Strategy and Quality)
Mrs Victoria Marshment (Authority Secretary)

Dr Emma Massey (Erasmus Medical Centre, Rotterdam)

Observers

Mr Peter Jones (Department of Health)
Mr Patrick Irwin (Department of Health)

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Item	Title	Action
Item 1	Welcome and apologies	
	<ol style="list-style-type: none"> 1. Baroness Warwick welcomed Members and observers to the fiftieth meeting of the Human Tissue Authority. 2. Apologies had been received from Mrs Rosie Glazebrook, Professor Gurch Randhawa and Dr Andrew Reid. 	
Item 2	Declarations of interest	
	<ol style="list-style-type: none"> 3. There were no declarations of interest. 	
Item 3	Minutes of 24 May 2011 [paper: HTA (33/11)]	
	<ol style="list-style-type: none"> 4. The minutes of 24 May 2011 were adopted. 	
Item 4	Matters arising	
	<ol style="list-style-type: none"> 5. All actions from the previous meeting had been completed or were in hand. 6. Business planning prioritisation, Serious Untoward Incidents (SUIs) and Freedom of Information (FOI) requests, and the assessment of living organ donations were discussed at the Members' Group meeting of 28 June. 7. A draft public facing communication on the retention of human tissue in Home Office cases will be shared with the Histopathology Working Group on 13 September. The agenda for this meeting will also include an item on the facilitation of communication between Home Office pathologists and mortuaries. 8. An updated policy position on the absence of a presumed genetic relationship in living organ donations will be uploaded to the HTA's website. 9. The HTA's contribution to the Big Society will be discussed at the September Authority meeting. 	
Item 5	Chair's report	
	<ol style="list-style-type: none"> 10. The Chair gave an update on the appointment of the new Chief Executive. Alan Clamp, the HTA's Director of Regulation, has been appointed to the role of Chief Executive. Due to remaining leave entitlement the current Chief Executive's (Craig Muir) last day will be 19 August. Handover is underway. Sue Martin will take responsibility for strategic issues while both Craig and Alan are on leave at the end of August. 	

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	<p>11. The Director of Regulation post is now vacant and has been advertised both internally and within the NHS and civil service pools. Interviews are scheduled for early August.</p> <p>12. The First Minister of Wales announced his legislative programme on 12 July which included a Bill to introduce presumed consent for organ donation in Wales. Vicky Marshment will be representing the HTA on the Expert Panel which has been established by the Welsh Assembly Government. It was confirmed that the aim of this legislation was to increase rates of deceased organ donation in Wales. The legal implications of the proposed change in legislation will need to be fully explored by the Expert Panel prior to the publication of a White Paper consultation at the end of 2011. It was noted that the Health Minister in Northern Ireland is also considering a move to presumed consent.</p> <p>13. BBC London news recently ran a story on a SUI at Hammersmith hospital, the HTA media team worked with journalists to ensure the story was balanced.</p>	
Item 6	ALB review and shared services update [paper: HTA (34/11)]	
	<p>14. Craig Muir introduced the paper which provided background on the ALB review and an update on progress. The HTA continues to promote the benefits of keeping our functions together and the Department of Health has been receptive to this suggestion.</p> <p>15. The ALB Review document published in July 2010 gave an indicative date of April 2013 for the transfer of HTA functions to other organisation(s). In recent discussions with the Department of Health, 2014 has been suggested as a more likely transfer date, although this may still be challenging.</p> <p>16. The HTA will continue to be a dynamic and forward looking organisation, ensuring public confidence in the safe and ethical use of human tissue.</p> <p>17. The HTA is involved in the Department of Health's shared services agenda to ensure back office functions are as efficient as possible.</p> <p>18. No sovereign powers of the Authority will be removed during the transition period.</p> <p>19. Members expressed the view that whichever organisation(s) takes over the HTA's function(s), must have the capacity to do so efficiently and effectively. It was</p>	

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	<p>noted that recent media coverage of the Care Quality Commission (CQC) displayed the breadth of the organisation's remit and the problems experienced in meeting current regulatory obligations. It was explained that work is underway with the CQC's sponsor team at the Department of Health, and the CQC, on the arrangements for any transfer of functions and the retention of expertise.</p> <p>20. The Department of Health explained that the impact assessment on the proposed changes had not yet been completed and this will be published with the consultation document on the preferred option for transfer.</p> <p>21. Members stressed the importance of the information in both the consultation document and impact assessment being accurate and reflective of the HTA. It was noted the desire to reduce the burden on regulated establishments should not undermine statutory provisions which seek to protect the public, service users and society more broadly.</p> <p>22. Assurances have been given that any efficiency savings made by the HTA over coming months and years will be attributed to the steady-state organisation, and not the transfer process.</p> <p>23. The HTA continues to work with the CQC, Human Fertilisation and Embryology Authority (HFEA) and the Medicines and Healthcare products Regulatory Agency (MHRA) to reduce the burden on regulated establishments.</p> <p>24. The Authority noted the contents of the paper.</p>	
Item 7	Update on the implementation of the Organ Donation Directive [paper: HTA (35/11)]	
	<p>25. Alan Clamp introduced the paper which provided background information on the European Union Organ Donation Directive (EUODD) and an update on its implementation by the HTA as Competent Authority.</p> <p>26. The twelve week public consultation on the draft Statutory Instrument and Directions will now start in September 2011, a month later than previously scheduled.</p> <p>27. The paper identified the risk status of the EUODD project as being amber, it was noted that due to tight timescales it is unlikely that the project status will ever achieve green.</p> <p>28. Members commended the team working on the EUODD for the work delivered so far.</p> <p>29. The first meeting of all European Competent Authorities for the EUODD will be held in late September/early October and will provide an opportunity to share best practice.</p>	

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	30. The Authority noted the contents of the paper.	
Item 8	Regulatory Activity Report 1 April to 30 June 2011 [paper: HTA (36/11)]	
	<p>31. Alan Clamp introduced the paper which had been discussed by the Regulation Members' Group (RMG) on 13 July.</p> <p>32. There had not been any critical shortfalls since this classification was introduced in November 2010.</p> <p>33. In the first quarter of 2011/12 there had been three investigations, one Regulatory Action Panel (RAP) and 12 SUIs and 24 Serious Adverse Events and Reactions (SAEARS). Reporting times indicate communications from the HTA on the importance of rapid reporting have been effective.</p> <p>34. An update was given on the establishment referenced in paragraphs 29-31 of the report, confirming that evidence had been provided by the stipulated deadline that consent standards were now fully met.</p> <p>35. Members were pleased to note a fall in the number of SUIs and SAEARS against the previous quarter. The HTA has shared learning in this area with regulated establishments through the quarterly newsletter, the lessons learnt section of the Post Mortem Audit Report and the inspection process.</p> <p>36. It was explained that the two month deadline for an establishment to submit their SUI internal investigation report to the HTA was an upper limit and many were received well ahead of deadline. Some establishments classify a wider range of events as being an SUI for internal reporting. The quality of an investigation should not be compromised by shorter submission deadlines, it was confirmed that dialogue between the HTA and the establishment is maintained to ensure a high quality investigation is conducted as rapidly as possible.</p> <p>37. The Authority noted the contents of the report and thanked the author.</p> <p>Action: Classification of SUIs to be discussed at the Histopathology Working Group meeting on 13 September.</p>	AC
Item 9	Framework for living organ donation assessment - update [paper: HTA (37/11)]	

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	<p>38. Allan Marriott Smith provided background information on this issue and detailed the previous discussions of the Authority on this matter.</p> <p>39. Emma Massey gave a presentation on altruistic donation at the Erasmus Medical Centre in Rotterdam. Key messages were:</p> <ol style="list-style-type: none"> i. Over 50% of all kidney donations were from living donors. ii. This figure was over 70% at the Rotterdam centre. iii. There are more unrelated living donors than related living donors. iv. Most unrelated donors donate to their partner. v. Altruistic donors can choose to donate to the national waiting list, to trigger a chain of domino paired donations, or to direct their donation to a person with whom they have no genetic or emotional relationship. vi. There are national guidelines on the screening of living donors, these outline what must be done but do not stipulate how to do it, which is decided regionally. vii. The same approach is taken for all donors, there is no differentiation on the basis of relationship. viii. A psychosocial assessment of the donor is conducted by the coordinator and a Social Worker. ix. The decision on whether to proceed with the donation is made by the clinical team. x. An additional psychiatric assessment of altruistic donors is required. xi. Between 2000-2010, ten people have chosen to direct their donation to a person with whom they have no genetic or emotional relationship. <p>40. Examples of donations between people with neither a genetic or emotional relationship included a mother seeing another mother fainting in the school playground and, on learning that she needed a transplant, offering to donate; and a neighbour noticing dialysis fluid being delivered regularly to a local resident, and this prompting them to offer to donate.</p> <p>41. There are no formal mechanisms to ensure consistency across the Netherlands. However, both the Dutch Transplant Foundation and the national meetings of Nephrologists allow the sharing of best practice. There is</p>	
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	<p>no equivalent to the HTA assessment of living organ donations in Holland.</p> <p>42. Allan Marriott Smith then introduced the paper, which reflected the solution sketched out at the Members' Group meeting on 28 June. The framework seeks to provide assurance to the HTA that the donor has been offered no reward or been put under duress or coercion, while also being proportionate to the risk of these events occurring. There would be some costs associated with developing and implementing the framework, and ongoing costs for additional psychiatric assessments. The proposed framework would mean an expansion of the Independent Assessor interviews, and the HTA's IT systems would need to be updated.</p> <p>43. Members congratulated Allan and his team on the proposed framework. It was suggested that the proposed psychiatric report (for donors with no genetic or emotional relationship with the recipient) should build on the existing altruistic donor report and seek to establish their motivation and whether they were attempting to conceal anything. Further investigation of the Dutch system of psychosocial assessments was suggested.</p> <p>44. It was noted that living transplant units already do a great deal of work to establish whether a donor is financially motivated or being pressured to donate, and we should not seek to replicate this, but rather codify it.</p> <p>45. Future engagement on this matter should tease out the concept of a relationship.</p> <p>46. There was support for the risk based and proportionate framework proposed, and it was thought that once the risk matrix was established, it would be quick and easy to work with.</p> <p>47. If the HTA discovered a breach of the Human Tissue Act, the Standard Operating Procedure (SOP) for police referrals would be followed.</p> <p>48. The Authority approved the proposals and key milestones as detailed in the paper.</p> <p>Action: To further investigate the psychosocial assessment carried out in the Netherlands.</p> <p>Action: To update the police referrals SOP as necessary.</p>	<p>AMS</p> <p>AMS</p>
<p>Item 10</p>	<p>Report on the living organ donation system – January to June 2011 paper: HTA (37/11)]</p>	

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	<p>49. Allan Marriott Smith introduced the paper and noted that 588 living organ donation cases had been received between January and June 2011, an increase of 32 on the same period last year.</p> <p>50. 87% of cases are now fit for purpose at the point of submission, which saves time and effort for all those involved.</p> <p>51. The Authority noted the contents of the paper.</p>	
Item 11	Financial Report June 2011 [paper: HTA (39/11)]	
	<p>52. Sue Martin introduced the paper which covered the first quarter of 2011/12.</p> <p>53. Capital funding had been granted by the Department of Health for the IT changes required to implement the EUODD. £113k of revenue funding had also been made available to cover costs associated with the EUODD and to ensure there is no cross-subsidy from other sectors.</p> <p>54. The surplus identified is due in the main part to the prudent forecast of income from the Human Application sector. Establishments are carrying out more activities than estimated, resulting in the surplus.</p> <p>55. There are also a number of vacant posts being held open until efficiency plans and resource modelling is completed and a decision made on the precise number of staff required to achieve this year's business plan.</p> <p>56. The under spend this year will require licence fee credits, as in 2010/11. Treasury guidelines stipulate that must be made in-year. the HTA meets this requirement by issuing a credit note in-year and deducting that amount from the following year's licence fee.</p> <p>57. The focus placed on debt recovery has made an impact with a decline in the number of debtors against the previous year. Appropriate legal action will be taken against those which remain.</p> <p>58. The Authority noted the contents of the paper.</p>	
Item 12	Report from Audit Committee 2 June 2011 [paper: HTA (41/11)]	
	<p>59. Michael Banner introduced the paper which included the minute of the Audit Committee meeting on 2 June and formed the Committee's annual report to the Authority.</p> <p>60. The reports from the internal auditors, RSM Tenon, and the National Audit Office (NAO), had been positive. In line with the shared services agenda, Grant Thornton will be the</p>	

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	<p>HTA's internal auditors for 2011/12 onwards.</p> <p>61. Members thanked Sue Martin and her team for the hard work done over the past year to ensure such successful outcomes.</p> <p>62. The Authority noted the contents of the paper.</p>	
Item 13	Strategic Performance Review June 2011 [paper: HTA (42/11)]	
	<p>63. Allan Marriott Smith introduced the paper and provided further information on the KPI on vacancy rates and staffing levels.</p> <p>64. The 2011/12 business plan remains deliverable with the current number of staff, taking into account planned departures. However, it was acknowledged that this is becoming an increasingly challenging task.</p> <p>65. Work on efficiencies is underway across the HTA, including the Regulation directorate, to establish the precise number of staff required.</p> <p>66. Advertisements have been placed in the national press for Regulation Managers. At least one will be recruited (suitable candidates permitting) and more if required, based on the results of the modelling work on efficiencies.</p> <p>67. The Authority noted the contents of the paper.</p>	
Item 14	Report on enquiries 1 April to 30 June 2011 [paper: HTA (42/11)]	
	<p>68. Shaun Griffin introduced the paper which gave an update on the HTA's handling of enquiries.</p> <p>69. The average response time is now 4.7 working days, against 7.3 working days for the same period last year. Updates are being made to IT systems to allow reporting against a maximum response time of 10 days for enquiries.</p> <p>70. It was noted that the two complaints listed in the report were not complaints against the HTA, but against licensed establishments. It was agreed that these should be described as 'referrals' in future.</p> <p>71. Paragraph 6(e) should read "not being available", rather than "not being unavailable".</p> <p>72. The fall in the number of body donation enquiries was noted. In part this was attributed to the work done last year to develop an online system to search for local anatomy schools by postcode.</p> <p>73. Approximately 50% of FOI enquiries are from the media, the bulk of the remaining 50% are seeking information on licensed establishments or requesting unpublished</p>	

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	<p>inspection reports. There are a small number on the administration and finances of the HTA.</p> <p>74. The Authority accepted the paper for information.</p> <p>Action: Complaints against licensed establishments to be reported as referrals in future.</p>	SG
Item 15	Update on the Communications Strategy (Oral)	
	<p>75. Shaun Griffin gave Members an oral update on the implementation of the Communications Strategy. A written report, including key information on enquiries, will be an agenda item at the September meeting.</p> <p>76. Sarah-Jane Wakefield had joined the HTA as Head of Communications in June 2011, and much of her and the team's work has been focussed on the Review of the Year event and Annual Review document.</p> <p>77. Twitter and Facebook accounts were set up in June and are being used on a regular basis.</p> <p>78. A proactive article in the Observer on altruistic donation led to other media opportunities and has reportedly led to an increase in enquiries to transplant units from potential donors.</p> <p>79. Two press releases had been issued: one on the Post Mortem Audit Report, and another on Alan Clamp's appointment as Chief Executive.</p> <p>80. A public engagement project is planned for later in the year.</p>	
Item 16	Any other business	
	<p>81. Diana Warwick noted this was Craig Muir's last Authority meeting and thanked him for his hard work and commitment to the HTA.</p> <p>82. Craig thanked the Board and the team in the office for all their enthusiasm and support, and was pleased to be able to handover to Alan Clamp.</p>	
Item 17	Question and Answer session	
	83. A question and answer session followed the main meeting.	

The meeting closed at 1.00 pm

Authority paper

Date	27 September 2011	Paper reference	HTA (44/11)
Agenda item	6	Author	Alan Clamp

ALB review and shared services update

Purpose of paper

1. A detailed paper relating to the Arm's Length Bodies (ALB) review and shared services was discussed at the Authority meeting in July 2011. This paper provides the Authority with a short update of the activities arising from the review of ALBs and developments on the shared services agenda.

Action

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

ALB review

3. The Department of Health (DH) intend to consult on the transfer of the HTA's functions by the end of the year. The DH has confirmed that the preferred option presented in the consultation document will be that all the functions of the HTA will transfer to the Care Quality Commission (CQC).
4. The DH have been considering how to manage engagement with stakeholders and has separated organisations into three tiers.
 - Tier one comprises the HTA, Human Fertilisation and Embryology Authority (HFEA), CQC and the Devolved Administrations. The DH will share the contents of the draft consultation document with these bodies to permit checks for factual accuracy. At present, no date for this has been set and it is not clear whether the HTA will have access to the whole document or how long we will have to respond.

- Tier two comprises other bodies presented in the consultation document as possible destinations for some functions as an alternative to the preferred option of keeping the HTA's functions together, such as the Medicines and Healthcare products Regulatory Agency (MHRA). The second tier also includes leading opinion formers, such as the British Medical Association or the Anthony Nolan Trust. The DH will actively seek the views of stakeholders in tier two during the consultation process.
 - Tier three comprises other bodies and individuals who will not be directly engaged by the DH, but whose attention will be drawn to the consultation document.
5. The consultation document will be accompanied by an impact assessment, which is being developed by the ALB Team at the DH. This impact assessment will describe, and quantify in financial terms where possible, the likely structure, functions and operating costs of the HTA at the anticipated date of merger with CQC in 2014. The Acting Chief Executive Officer and Director of Resources at the HTA have provided information to the ALB Team to inform the development of the impact assessment and it is likely that we will see a first draft at the same time as seeing the consultation document.
6. Members will be kept informed about developments on the consultation document and impact assessment, and will be consulted on how the HTA should respond to the ALB consultation when it is published later this year.

Developments with CQC and HFEA

7. The Authority paper on 24 May 2011 referred to a meeting SMT had with CQC representatives on 12 May to review development and discuss plans for working together in areas of potential synergy. To support this approach we agreed with CQC and HFEA that we will adopt a strategic partnership agreement which will set out the principles of working together on a tripartite basis, to ensure the most efficient use of our combined resources, to ensure a joined up approach with the other bodies, and to reduce the burden on those we regulate. The CQC have recently suggested that separate bipartite agreements with the HTA and the HFEA may be more effective from their point of view and this will be discussed further at the next meeting of the three organisations on 3 October. In the meantime a working group has been established to look at how we can collaborate more with CQC and HFEA in terms of our regulatory activity, with a specific focus on sharing information about establishments.

Shared services

8. There have been very few developments regarding shared services since the Authority meeting in July 2011. The DH is reviewing the information collected about legal services and Human Resources (HR) before communicating the proposed next steps. We await further details about the collaborative HR model.
9. HTA staff visited CQC to find out more about their transition to shared services and the associated costs and benefits. This has helped us start to determine implications for the HTA. We will have further discussions with CQC after their transition in October about what would need to happen for an HTA transition to finance shared services.
10. The HTA has started using central contracts for office supplies and other central contracts will be considered as the need arises.

Authority paper

Date	27 September 2011	Paper reference	HTA (45/11)
Agenda item	7	Author	Alan Clamp

Update on the implementation of the European Union Organ Donation Directive

Purpose of paper

1. To update the Authority about progress on the implementation of the European Union Organ Donation Directive (ODD) by the HTA in its role as the Competent Authority (CA) for all four countries of the United Kingdom.

Action

2. The Authority is asked to note the content of this report and of the oral update presented at the meeting.

Background

3. The ODD requires implementation into UK law by 27 August 2012. The underlying objective of the ODD is to ensure that EU member states introduce a framework for quality and safety in order to maximise the benefits of transplants and minimise the risks. The assurance that each member state is working to the same quality and safety requirements will also facilitate the exchange of organs between member states.
4. The HTA and the Department of Health (DH) will soon be consulting on the Statutory Instrument (Regulations) that will transpose the Directive into UK law and on the Regulatory Framework that sets out the requirements that must be met to ensure compliance with the Directive.

Key future milestones

- Eight or twelve week public consultation on the Regulations and Framework: September to November/December 2011
- Stakeholder engagement workshop on managing serious adverse events and reactions: October 2011
- Revised Regulations and Framework: December 2011
- Licensing fees announced: December 2011
- DI training workshops: January and March 2012
- Parliamentary approval of the regulations: March 2012
- Regulatory framework in place: March 2012
- Licensing of transplantation activities: April to August 2012
- Implementation of the Directive: 27 August 2012

Current position

5. The project status is currently AMBER. This status is primarily a reflection of the demanding timescales required for processes to be completed to ensure successful implementation by 27 August 2012. Substantial action is in place to mitigate this inherent risk.
6. Alan Clamp will provide an oral update to the Authority at the meeting on 27 September 2011, focusing on the consultation process and key risks, mitigating actions and contingency plans associated with the implementation of the ODD.

Authority paper

Date	27 September 2011	Paper reference	HTA (46/11)
Agenda item	8	Author	Vicky Marshment

Revision of the HTA's Codes of Practice

Purpose of paper

1. To provide the Authority with information on the planned revision of the HTA's Code of Practice on the donation of solid organs for transplantation, and the possible revision of the eight other Codes of Practice.
2. The discussion on the revision of the Code of Practice has been prompted by the implementation of the EU Organ Donation Directive (ODD).

Action

3. The Authority is asked to note the content of this paper and provide any comment.

Background

4. In March 2011 the HTA was appointed as Competent Authority for the ODD. The HTA will be the Competent Authority for England, Wales, Scotland and Northern Ireland.
5. The (draft) statutory instrument which will transpose the ODD into domestic legislation does not compel the HTA to publish a new Code of Practice.
6. The HTA publishes nine Codes of Practice in total, seven of which require approval of the Secretary of State and both Houses of Parliament. The two Codes of Practice which do not require this level of scrutiny are those covering disposal, and import and export.

7. The most recent versions of the Codes of Practice were published in September 2009, with the exception of the Code of Practice on import and export which was published in 2007.

Approach

8. A paper on the revision of the Codes of Practice was discussed at the HTA Management Group (HTAMG) meeting in August, and the decision was made to commence the revision of the Code of Practice on the donation of solid organs for transplantation as a matter of priority as this document will require the most extensive review in light of the ODD.
9. This Code of Practice also needs to be updated to reflect the legal advice the Authority received last year from Mr Fleming QC on living donations between people who have neither a genetic or established emotional relationship. Information on the adapted framework for assessment, which will be introduced in early 2012, will also need to be included.
10. The 12 week consultation on this Code of Practice will be active during the planned ODD Designated Individual (DI) training events which are scheduled for March 2012. This provides the HTA with an opportunity to directly engage those who will be affected by our regulation.
11. The draft Code of Practice, and an accompany report on the feedback from the consultation, will be discussed at the Authority meeting in May 2012.
12. It is intended that the Code of Practice will be laid in both Houses of Parliament for 40 days, as required by the negative resolution process, in June 2012.
13. This would allow us to publish the Code of Practice in August 2012. If the timeline slips we are able to publish a draft version on our website (which must be clearly marked as a draft) while this is laid in the Houses of Parliament, to enable our stakeholders and soon-to-be licensed establishments to access the revised Code of Practice.

Revision of other Codes of Practice

14. The other Codes of Practice do not require significant revision to reflect the ODD, and there is no intention to seek parliamentary approval when the only change required is an additional line at the beginning of the document stating that the HTA also regulates under the ODD. Instead, we will issue an update

to these Codes of Practice in August 2012 explaining this. This update would show on the online versions of the documents and would also be highlighted when these are printed out.

15. The HTAMG has requested a paper scoping the need for a revision of the remaining eight Codes of Practice and the resource/cost implications of this. This paper will consider the broad need for revision, rather than just focussing on the ODD. The paper will also consider whether the HTA should publish a Codes of Practice on the definition of death for the purposes of the Human Tissue Act (the Act). Listed in the Act at section 26(2) are matters which the Authority shall deal with in our Code of Practice, the definition of death is the only area which is not currently addressed.
16. The outcome of the discussions at the HTAMG meeting will be included in a paper for the Authority meeting in January.

Interim position

17. If the HTA is aware that a section of a Code of Practice requires amendment we have the option of publishing an update to that section. It must be clearly stated that this update does not have parliamentary approval.
18. Prior to a decision been made on the revision of the eight other Codes of Practice we will issue updates as necessary, taking into account the risk associated with not doing so. These will be reviewed by the Head of Legal before publication.
19. Once a section has been identified as needing amendment, we will place a note on the online version of the Code of Practice advising those accessing that section that they should contact the HTA directly for information. We will make establishments aware of areas which are being updated through our regular communication methods, including the e-newsletter.

Authority paper

Date	27 September 2011	Paper reference	HTA (47/11)
Agenda item	9	Author	Vicky Marshment

Report on the introduction of presumed consent in Wales

Purpose of paper

1. To provide the Authority with information on the proposal to introduce presumed consent for deceased organ donation in Wales.

Action

2. The Authority is asked to approve the proposals set out in paragraphs 23-25.

Background

3. The Welsh Government introduced a Legislative Competence Order (LCO) in January 2011 which requested standing to introduce legislation on a system of presumed consent for deceased organ donation in Wales. Following a referendum in May, the Welsh Government can now legislate directly on all devolved matters, including health.
4. The HTA responded to the brief consultation run by the Welsh Government in January (Annex A) and to the Welsh Affairs Select Committee in February (Annex B). The evidence submitted (by the HTA and others) to the Welsh Affairs Select Committee is published on their website, however the inquiry did not take place as the referendum rendered it obsolete.
5. In both documents the HTA raised questions and queries, but did not take a view on the proposal to introduce presumed consent.

6. The First Minister of Wales announced his legislative programme for the coming year in July. The introduction of presumed consent was a central part of the programme.
7. The HTA was invited to join the Organ Donation Bill–Expert Reference Panel (ODB-ERP) in July this year. This invitation was accepted and meetings were held on the 1 and 31 August, and 26 September.
8. The HTA wrote to the Chair of the ODB-ERP confirming that our role on the Group is purely advisory, and our membership does not constitute support of the proposal to introduce presumed consent, or any specific recommendations which are generated by the Panel.
9. Five stakeholder events have been held during August and September. Those working within the NHS, voluntary groups, and professional bodies were invited to take part. The HTA was represented at one of these events, which was attended by those working in the NHS.
10. Feedback from these meetings will be provided in an oral update to the Authority.
11. The Welsh Government intends to publish a White Paper on the introduction of presumed consent during the autumn of 2011.

Welsh Government Proposals

12. As the White Paper is yet to be published it cannot be stated with certainty how the Welsh Government will propose to implement a system of presumed consent.
13. From the information contained in the LCO it is likely that the proposal will be to introduce a soft opt-out system, that is one in which the family of the deceased/soon to be deceased are asked to confirm the views of that person. This is opposed to a hard opt-out system, where the family are not consulted.
14. The LCO also proposed that the presumed system would not apply to everyone who lived in Wales. It detailed that children, people lacking the capacity to consent, and people not ordinarily resident in Wales would not be included within the remit of the proposed legislation. Welsh residents who died outside Wales would be subject to the consent provisions of the country in which they died (so a Welsh resident who died in a hospital in Liverpool would not be presumed to have consented to organ donation, but rather Human Tissue Act 2004 (the Act) consent would be sought).

15. No information was provided on how an individual would find out whether presumed consent applied to them, or how they would go about opt-ing out.
16. Little information was put forward on the cost of implementing this policy, or the expected year on year increase in donors it would yield.
17. A regulatory impact assessment was not published in January when the LCO was laid, and no information on the regulatory impact of this policy has been made available by the Welsh Government.
18. The HTA understands that when the LCO on presumed consent was laid in January the Attorney General requested advice on whether consent to organ donation was a health matter or a human rights matter. While health is a devolved matter, human rights are not, and only the Westminster Government can legislate on human rights on behalf of the people of Wales. The Attorney General has not yet published any information on the proposal to introduce a system of presumed consent in Wales.

HTA position

19. At present the HTA position on presumed consent is that stated in the two documents published earlier this year.
20. In early September we accepted a request for a pre-recorded interview with BBC Radio Wales to ensure that position of the HTA was fairly represented. The radio programme, "Eye on Wales", which focussed solely on the issue of presumed consent was broadcast on 18 September and a link has been circulated to Members.
21. The primary concern for the HTA is likely to rest on whether the proposed implementation of presumed consent in Wales protects the wishes of the individual in life, to mirror the central provision of the Act. If the systems which are to be introduced do not easily allow an individual to be certain whether presumed consent applies to them, and barriers are put in place to opt-ing out (whether perceived or actual), this would mark a significant move away from the principles which the HTA are charged with protecting and upholding.

Proposed next steps

22. Following the publication of the Welsh Government's White Paper the HTA will need to make a decision as to whether to respond to this.

23. The decision on whether to respond may rest on whether the HTA can offer further assistance to the Welsh Government in their efforts to introduce presumed consent. We may also wish to consider whether as an interested party there would be merit in taking part in the broader discussion on this matter.
24. If the White Paper is published prior to the Authority meeting on 22 November an options paper will be drafted for that meeting to facilitate a discussion on how the HTA will respond to it, if at all. Dependant on when the White paper is published it may be necessary to circulate this paper less than a week prior to the meeting.
25. It is recommended that the HTA continues to respond to requests for information from the media, and makes a decision whether to accept bids for interviews on a case-by-case basis.

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

Annex A

HTA (47/11)



Human Tissue Authority
151 Buckingham Palace Road
London
SW1W 9SZ

Tel 020 7269 1900
Email enquiries@hta.gov.uk
Web www.hta.gov.uk

Date 21 January 2011

BY EMAIL AND POST

Dear

Thank you for giving the Human Tissue Authority (HTA) the opportunity to respond to your consultation on the draft Legislative Competence Order (LCO) relating in organ and tissue donation for the purposes of transplantation.

We note the National Assembly for Wales' acknowledgement that this is a brief consultation period, and this letter constitutes the initial considerations of the HTA. We intend to respond to calls for evidence from other committees involved in the pre-scrutiny process.

As the watchdog which has responsibility for ensuring that organs and tissue are only removed for transplantation with proper consent in England, Wales and Northern Ireland, we have an interest in this LCO and the associated memorandum which gives details of the proposed process.

Under the Human Tissue Act 2004 consent must be in place before organs and tissue can be removed from a deceased person for the purpose of transplantation. Failure to obtain this consent is a criminal offence.

The proposed LCO would give direct legislative power for the Welsh Assembly Government to make its own legislation for the purpose of consent or authorisation for the removal, storage or use of human tissues or cells (apart from embryos, gametes, hair and nails) from a deceased person of at least 18 years at time of death for the purpose of transplantation to a human body. The one exemption given is that where a Coroner is involved, the consent for such activity must come from the Coroner.

Legal issues

We note that a regulatory impact assessment has not been carried out. This omission means the proposed LCO may not reflect the statutory implications which would affect the Human Tissue Act on consent, and the existing offence of removing material without

consent. We urge the National Assembly for Wales to carry out a regulatory impact assessment as a matter of urgency.

The HTA has not been actively consulted on this LCO and the proposed move to a soft opt-out scheme, prior to this short consultation exercise. We believe that earlier consultation would have been beneficial to all parties to ensure that there was no possibility of duplication of regulation, or confusion on the remit of various organisations (HTA, NHSBT, National Assembly for Wales). We will continue to engage with the pre-legislative scrutiny process on this LCO as it progresses.

The proposed LCO seeks to make consent or *any other authorisation* a matter for the Welsh Assembly Government. There is no definition of “any other authorisation” given in either the Order itself or the memorandum which accompanies it. We assume that this is to allow the introduction of the soft opt-out system detailed, however it is important that the precise intention of this form of words is shared as a matter of priority, to ensure that pre-legislative scrutiny is as robust as possible.

Practical issues

We have only commented on those practical issues which have a link with the Human Tissue Act, and are therefore within our remit.

The memorandum details the soft opt-out system would only apply to those who live and die in Wales, and excludes from this group those under 18 and adults who lack capacity. People who die in Wales but did not live there, all under 18s and adults who lack capacity will be subject to the Human Tissue Act’s provisions on consent. Organ donation teams in Welsh hospitals will need to be trained on both systems and able to identify which group a deceased, or soon to be deceased, person is in. We are concerned that introducing complexity, and potentially confusion, to a system which works well could diminish people’s confidence in organ donation and consent more widely.

The associated risk of the wrong system being applied to a person and an offence being committed should also be considered, and an explanation given of the steps that would be taken to mitigate this.

Although point six of the memorandum states that “The Welsh Assembly Government wishes to increase the number of organ and tissue donors in Wales to improve both the health and quality of life of citizens” there is no evidence provided to substantiate the fact that the introduction of a soft opt-out scheme will do this. If there is to be a move away from the current position of an opt-in system under the Human Tissue Act, with the associated protections given to the individual’s wishes and consistency in consent requirements, it must have a solid evidence base.

No mention is made in the memorandum of the effect of an individual’s decision to opt-out during life. Would their family members still be approached to establish whether they will consent to organ donation (under the Human Tissue Act) or will the decision to be opt-out be taken as a definite and enduring “no”? It is important that this is made clear as a matter of priority to allow full consultation of the practical implications of this LCO.

It should also be noted that at present when consent is sought for organ donation, it is normally also sought for research. As research would remain a Human Tissue Act issue in Wales the family would be required to actively consent to this, potentially introducing confusion at an emotional time.

Point 14 of the memorandum notes that living organ donation entails a healthy person undergoing major surgery, and that the NHS incurs costs associated with the procedure and aftercare. The HTA gives approval for all living organ donations in this country and has over five years experience of this type of donation. We would point to the fact that outcomes in living kidney transplants are better than from deceased transplants and the dialysis costs for these patients are either removed completely or significantly reduced. Living organ donation has many positives and it would not be of benefit for it to be viewed as anything other than an equal partner to deceased donation for those requiring a kidney transplant.

There are a number of questions identified above which require answering before the proposed LCO can be thoroughly scrutinised and the HTA would welcome the prompt response of the National Assembly of Wales on these.

Yours sincerely

Craig Muir
Chief Executive

Human Tissue Authority evidence to the Welsh Affairs Committee on Organ Donation Legislative Competence Order

Date 28 February 2011

- The Human Tissue Authority (HTA) welcomes the opportunity to make this submission to the Welsh Affairs Committee (WAC).
- We have addressed those matters which are linked to the Human Tissue Act 2004 and within our remit. We have clearly indicated which of the questions posed by the WAC we have responded to.
- Issues not addressed in the questions, but which we believe are significant and would aid the pre-legislative scrutiny process, are detailed in the Additional Considerations section at the end of this document.
- The key points to note are:
 - No compelling evidence has been presented to demonstrate the move to an opt-out system in Wales will increase the number of organs available for transplantation.
 - There is a risk of public uncertainty as to whether or not an individual is affected by the opt-out system.
 - There is a risk that the “wrong” sort of consent is taken, which could lead to surgeons committing an offence under the Human Tissue Act.

Question 4 – *To what extent is there a demand for legislation on the matter(s) in question?*

1. There is little, if any, convincing data provided which suggests that there is demand for legislation on an opt-out organ donation scheme from the Welsh population. There is however, a growing demand for organs with people dying each day waiting for a transplant. Efforts to increase organ donation should be encouraged, but such a significant change to the consent process should only be considered in the light of compelling evidence.

2. The memorandum quotes statistics from a number of research projects, indicating that the majority of people support organ donation. A commonly quoted statistic is that over 90% of people support organ donation, while only 28%¹ have signed the Organ Donor Register (ODR).
3. It is of value to look a little further at the statistical evidence available. A recent HTA survey, conducted on our behalf by Ipsos MORI, found that 62% of people surveyed were either fairly likely, very likely, or certain to donate their tissue or organs for use in transplantation after their death. 25% of people were either fairly unlikely, very unlikely or certain not to.² With at least a quarter of those surveyed expressing an unwillingness to donate (a further 6% did not know how they felt on this issue) a move to presuming consent would appear premature.
4. It should be noted that the responses to the Ipsos MORI survey were given with the current opt-in system in operation. Many of the concerns that people express when the issue of an opt-out system is discussed were unlikely to be at the front of their minds when responding.
5. Spain is often cited as an example of a country which has both an opt-out system and high rates of deceased donation. The opt-out system was introduced in 1979, however the significant increase in donation rates took place during the 1990s. The director of the national transplant organisation in Spain was clear that the increase was not linked to the introduction of the opt-out scheme, but was likely to be linked to the implementation of a comprehensive national procurement system.³ A number of the recommendations of the Organ Donation Taskforce were based on the successful system which operates in Spain.
6. Not all countries which have an opt-out system in place have high rates of donation. Greece is an example of a European country where citizens are presumed to consent to organ donation, but the rates of deceased donation are low at 8.9 people per million, compared to 14.7 people per million in the UK.⁴
7. The results of the Welsh Assembly Government's public debate on organ donation, held between October 2008 and January 2009, point towards the most popular organ donation system being that of mandated choice with support from 27% of respondents, with an opt-out scheme garnering 22% support. This is a clear indication that there is a desire of respondents to be able to make a positive choice, and for there to be compulsion to make a

¹ <http://www.organdonation.nhs.uk/ukt/default.jsp> - 22 February 2011

² http://www.hta.gov.uk/db/documents/HTA_General_Public_report_FINAL_221010.doc

³ http://www.organdonation.nhs.uk/ukt/newsroom/statements_and_stances/statements/opt_in_or_out.jsp

⁴ 2008 statistics – Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation

decision either way. Without substantive evidence that an opt-out scheme will increase the number of organs available in Wales, and having consulted on this issue, the case does not seem to be made to introduce anything except the most popular alternative to the status quo, which is mandated choice.

8. Only 316 people expressed a preference for an alternative organ donation scheme, so the 22% who support the introduction of an opt-out scheme represents just 69 people. This small sample size means that there can be less certainty as to the proportion of the entire Welsh population who would support the proposal.
9. The memorandum which accompanies the proposed LCO explains that the aim of the National Assembly for Wales is to increase the number of organs available for transplantation. No clear evidence is presented that the implementation of an opt-out scheme in Wales would do this.
10. There is undoubtedly, however, a need for more organs to be made available. Across the UK three people a day die waiting for an organ;⁵ this data only includes those who were on a waiting list at the time they died, and not those who under current listing criteria are not deemed suitable. The opt-out scheme proposed has not been found to conclusively increase the number of available organs, without such evidence a move away from the implementation and delivery of the recommendations of the Organ Donation Taskforce and the work of the Programme Delivery Board would seem premature. There are significant risks in moving from one system which is yielding results to another which is unproven and which will incur significant costs during implementation.
11. The Ipsos MORI research also showed that those surveyed were more likely to donate when they knew regulation was in place. 52% of those surveyed stated they would be more confident to donate an organ or organs if they knew the system was regulated. This evidence suggests that ensuring the public are aware of the regulatory framework brings confidence in donation and is an important consideration when seeking to raise donation rates. It is likely to be more difficult to communicate the regulatory framework when consent is no longer a positive act, but rather indicated by silence.

Question 5 – *Are there any cross-border issues relating to the LCO? (e.g. financial or policy issues); and*

Question 11 – *Does the LCO have the potential to cause confusion regarding legal jurisdiction and the individuals to whom any Measure would apply.*

⁵ <http://www.organdonation.nhs.uk/ukt/default.jsp> - 22 February 2011

12. This LCO introduces both cross-border issues and potential confusion. We have addressed questions five and eleven together.
13. The HTA is the statutory regulator responsible for ensuring that organs and tissue are only removed for transplantation with consent in England, Wales and Northern Ireland. While we do not have jurisdiction over this matter in Scotland, it should be noted that the organ donation system is consistent, with all four home nations operating an opt-in system.
14. The ODR which is run and maintained by NHS Blood and Transplant (NHSBT) covers England, Scotland, Wales and Northern Ireland. Specialist Nurses for Organ Donation (SN-ODs) currently consult the ODR when they are informed there may be a suitable donor at their Trust. The information as to whether the person had signed the ODR or not, and any specific choices they have made, is shared with their family and friends to give them an indication of the person's wishes.
15. Under the opt-out system proposed by the National Assembly for Wales it would be necessary for a separate, additional register to be kept of those people subject to the system (those over 18, who live and die in Wales, who are competent). The introduction and maintenance of such a register would be at a cost drawn from public funds. SN-ODs would need to consult this register to establish whether they would be applying the Welsh system or not. If the potential donor was not on this list then the SN-OD would be seeking consent under the Human Tissue Act.
16. The Citizen Information Project, commissioned in 2004, established that the cost of a national population register would be in the region of £2.4bn. Although the register of those affected by the proposal would be smaller, it should be noted that previous feasibility studies have found such registers to be costly and difficult to form and maintain.
17. SN-ODs are employed and trained by NHSBT. It will be necessary to train all SN-ODs on all systems, so that they are all available to work in Wales and the rest of the UK, and can explain the differences between the two systems to a family if required.
18. It is not clear from the information made available by the National Assembly for Wales how the capacity of the person before their death would be assessed. The proposal states that the opt-out system would not apply to those who lacked capacity prior to their death, rather this group of people would come under the jurisdiction of the Human Tissue Act. It would be possible to keep a register of those people ordinarily resident in Wales who permanently lack capacity, however it would be a much more difficult task for those whose lack of

capacity is temporary. More information is required to fully assess this aspect of the scheme, however it is an area where confusion may arise as to which system of consent is to be applied.

19. Under the Human Tissue Act it is an offence for a reward to be offered or sought for an organ.⁶ It is unclear if the consent requirements of the Act were to no longer apply in Wales, whether the scrutiny of the activity of donation, and the offences associated with it, would still be the responsibility of the HTA. Any separation of these responsibilities is likely to cause confusion and increase bureaucracy.
20. There will be the need for a communication campaign alerting people to the introduction of the new scheme. This will need to cover both Wales and England, with consideration given as to whether it should also be extended to Scotland and Northern Ireland. The primary purpose of this campaign in Wales will be to alert residents to the changes and provide them with information on how to opt-out, as well as the benefits of remaining opted-in. In England it will be need to focus on explaining that those who are not ordinarily resident in Wales will not be affected by it, meaning that there is no need to opt-out in case you die in Wales, and do not wish your consent to be presumed.
21. This communication campaign will have two very different aims and will be of significant cost. In 2008 the Organ Donation Taskforce identified the cost of a three year, UK-wide, communications campaign to be £25m.⁷ While the scale of the campaign under the proposed scheme would be smaller, it would clearly still cost millions rather than thousands of pounds.
22. The potential for confusion is considerable, and special attention will need to be given to communicating with those living in the English towns and villages which border Wales. The HTA believes that there will be a relatively high number of incidences of people seeking to establish whether or not they are on the list and consideration will need to given to how people are informed of this, and how requests for information will be dealt with.
23. There is a risk of the wrong system being applied. If the opt-out scheme is relied on for a person who in fact is subject to Human Tissue Act consent, then the surgeon who removes the organ or organs will have committed an offence.⁸ Surgeons will need to ensure they have suitable professional and legal indemnity in place in case of mistake. If such an error was made the HTA would be required to refer the case to the Crown Prosecution Service (CPS) for consideration.

⁶ s.32(1)

⁷ http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090310.pdf

⁸ s.5(1)

24. If the primary aim is to increase organ donation by ensuring families are aware of the potential donor's wishes, and therefore increasing their likelihood to consent, then this could be done more economically with increased promotion of the ODR and full implementation of the recommendations of the Organ Donation Taskforce. This would also have the benefit of not creating any cross-border issues.
25. In the absence of an impact assessment it is not clear how much the National Assembly for Wales expect this change will cost, however it would certainly require significant investment. If there was a guarantee that more organs would be made available, and less people would require dialysis, and those that do for a shorter period of time, then this may be seen as a proportionate step. However, in the absence of such evidence an increase in spend on the proposed scheme does not appear to be justified.
26. It should also be noted that at present when consent is sought for organ donation, it is normally also sought for research. As research would remain a Human Tissue Act issue in Wales the family would be required to actively consent to this, potentially introducing confusion at an emotional time.
27. There are also occasions when consent is sought to procure tissue for use in human application. This activity is governed by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and requires Human Tissue Act consent to be in place prior to the procurement.

Question 6 – Are the purpose and scope of the LCO clearly defined, including the terms and definitions used?

28. Broadly the purpose and scope of the LCO are clearly defined. The HTA has only one area of concern which is addressed below.
29. The proposed LCO seeks to make consent or *any other authorisation* a matter for the Welsh Assembly Government. There is no definition of *any other authorisation* given in either the Order itself or the memorandum which accompanies it. We assume that this is to allow the introduction of the opt-out system detailed, however it is important that the precise intention of this form of words is shared as a matter of priority, to ensure that pre-legislative scrutiny is as robust as possible.
30. We note that Report of the National Assembly for Wales Legislation Committee No. 1 recommends that the term "or other authorisation" is "deleted or replaced by another form of words that more clearly describes the powers that the

Welsh Government is seeking to acquire".⁹ The HTA welcomes this recommendation and awaits the outcome with interest.

Question 7 – Does the LCO have the potential to increase the regulatory burden on the private or public sector?

31. The LCO has the potential to increase the regulatory burden to the public sector, and has limited potential to reduce it.
32. There is no existing requirement that a register of potential donors is kept. While the ODR is both a record of people's wishes and a tool for the promotion of organ donation, it is not a statutory requirement.
33. It will be necessary under the proposed system to maintain a register of people ordinarily resident in Wales, and record whether they have opted-out. This will need to be a dynamic and robust register which takes the recommendations of the Review of the Organ Donor Register conducted by Sir Gordon Duff¹⁰ and implements them from the outset. This will impose an additional regulatory burden on the public sector.
34. The National Assembly for Wales has the benefit of the recommendations and guidance contained in Sir Gordon's report and should seek to apply them where applicable.
35. A standardised form is used in all hospitals in the UK to record the consent of the donor or their family and friends to donation, and in some cases research. It is unclear whether the National Assembly for Wales intends to continue the use of this form, or another one similar to it, or whether this requirement would be removed. In the case of removal this would reduce the regulatory burden. It would still be necessary however, to take details of the donor's medical and social history to ensure the quality and safety of the organ/s and/or tissue. This is currently standard practice and a requirement of the EU Organ Donation Directive which will be operational in the UK by August 2012. Therefore the removal of the need for a consent form to be filled in may not of itself significantly reduce the regulatory burden.
36. As noted in paragraph 17, NHSBT will require their SN-ODs to be trained on both the Welsh system and that which applies in the rest of the UK, increasing the regulatory burden on a public sector organisation.

Additional considerations

⁹ <http://www.assemblywales.org/cr-ld8395-e.pdf>

¹⁰ http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_120579.pdf

37. No mention is made in the memorandum of the effect of an individual's decision to opt-out during life. Would their family members still be approached to establish whether they will consent to organ donation (under the Human Tissue Act) or will the decision to be opt-out be taken as a definite and enduring "no"? It is important that this is made clear as a matter of priority to allow full consultation of the practical implications of this LCO.
38. When an individual signs the ODR they are able to choose whether they wish to donate all of their organs, or to select a specific organ or organs. It is not clear whether the proposed system will allow for this level of flexibility, e.g. could you opt-out for certain organs, but remain opted-in for others?
39. There is no information given on whether those affected by the proposed system will still be able to sign the ODR to express their wishes positively, and whether this will be checked as a matter of course as it is at the moment. There may be occasions where the two records are conflicting with the ODR showing a wish to donate, while the Welsh register shows a decision to opt-out. More information is needed in the relative status of the two registers.
40. As noted above it would be the surgeon who would commit an offence if the absence of opting-out is relied on, when Human Tissue Act consent should have been. In light of this it will be necessary to communicate with this group specifically if the proposed system were to be introduced, and there would be value in engaging with this group to fully explore practical issues prior to implementation.
41. The Human Tissue Act will need to be amended to introduce the proposed measure in Wales and a suitable legislative vehicle for this will have to be identified.

Signed



Craig Muir
Chief Executive
Human Tissue Authority

Authority paper

Date	27 September 2011	Paper reference	HTA (48/11)
Agenda item	10	Author	Allan Marriott Smith

Framework for living organ donation assessment - update

Purpose of paper

1. To provide the Authority with an update on progress with the implementation of the framework for the living organ donation assessment since the July Authority meeting.

Action

2. The Authority is asked to approve the proposals set out in paragraphs 12, 13 and 16.

Background

3. The HTA has a number of responsibilities in relation to the assessment of living organ donation applications. Among these, the Authority must be satisfied that:
 - i. no reward has been or is to be given in contravention of section 32 of the Human Tissue Act 2004 (prohibition of commercial dealings in human material for transplantation);
 - ii. there is no duress or coercion affecting the donor's decision to give consent.
4. Based on its experience of regulating living organ donations generally, the Authority has expressed concern that the risk of reward may be increased in directed donation cases where the relationship between the donor and recipient is outside of the 'usual' profile of donor recipient relationships, for example, where the relationship has been formed for the purposes of organ

donation. In view of the possible increase in the likelihood of reward, the Authority requires additional, proportionate, reassurance in these cases.

5. At its meeting in July the Authority agreed that an effective solution would comprise of three components, which would allow the Authority to be satisfied that the factors at 3(i) and (ii) were not present:
 - A more structured risk assessment to identify those cases where the risk of reward was perceived to be more likely. Such cases would then be assessed by a panel of three Authority members.

And for these higher risk cases:

- An, as yet to be specified, enhanced investigation process (e.g. psychological report exploring the motivation for directed donation).
 - Signed statements from the donor and recipient confirming that they understood the legal position in relation to reward.
6. It further agreed that review of the procedural changes after six months of operation would be prudent; providing an early opportunity to adapt the approach to take account of the experience of assessing these cases. The Executive would anticipate no more than half a dozen such cases to be assessed in the first six months.
 7. The implementation of such a framework becomes increasingly important over time as the HTA now receives more regular enquiries regarding our approach to handling more complex cases. The Authority will, for example, be aware of recent media coverage concerning a potential recipient who has been introduced to a potential donor through a US-based charitable foundation.

Progress since the July Authority meeting

8. The Chair and the Executive have had further discussions on the framework in light of the last Authority meeting and debate at the annual review event. These discussions have led to a number of conclusions which shape the proposals put forward in this paper:
 - i. The Authority's concerns relating to increased risk must be addressed and the components of the solution are still appropriate.
 - ii. The HTA does not yet have experience in assessing these cases, and making significant system changes runs the risk of having to make further changes (possibly quite quickly) as experience develops.

- iii. The HTA is keen to minimise the cost and impact of any changes both internally and importantly for partners outside, in particular the network of voluntary Independent Assessors.
- iv. The HTA should take an incremental approach to introducing the framework which would be piloted in the first six months.

Risk assessment framework proposal

9. The Authority has, on several occasions, noted the fact that there is a balance to be struck between basing a risk assessment on the more readily quantifiable aspects of a relationship (i.e. mother/son, brother/sister) versus the qualitative aspect of the relationship (i.e. the dynamics of a specific relationship). It is in the exploration of these qualitative aspects that the assessment process, in its entirety, seeks to tease out the likelihood that reward, duress and coercion are present in the donor's decision to donate.
10. While a more sophisticated risk assessment may be more effective in filtering the "right" cases for Authority scrutiny following enhanced investigation it also has a number of implications:
 - IA interviews/information gathering is required before a risk assessment can be made;
 - a decision on which cases to filter takes place later, rather than sooner, in the approvals process;
 - where risk scoring is involved, the subjective judgement of a member of Executive staff will be required to allocate a score which will itself be dependent on the quality of the information available from the IA.
11. These factors add complexity, come with an opportunity cost and arguably make the process less transparent.
12. We therefore propose to pilot a simplified risk assessment model (compared with the indicative model described at the July meeting) which can be issued in the form of guidance and applied at an early stage of the work up process by the Transplant Unit (with the advice of the Executive). This model makes explicit which categories of case the Authority wishes to scrutinise in greater detail. A suggested model is included at Annex A – and this should be developed by a meeting of the Independent Assessment Working Group (IAWG) on 25 October and will be brought for approval to the November Authority meeting.

Enhanced investigation process

13. The Executive will (with input from the October IAWG meeting) work during quarter three to develop a more concrete specification for the requirements of the psychiatric/psychological assessment. This will be linked with existing planned work to clarify the specification of psychological assessments currently undertaken in altruistic donation cases.

Legal statements

14. Draft statements for signature by donor and recipient will be developed (with input from the HTA's legal adviser) during quarter three.

Consultation

15. As we are piloting the approach in the first six months and the changes are relatively limited from the perspective of Transplant Units and Independent Assessors, we would not intend to undertake the wide consultation previously envisaged. However, subject to the approval of the approach outlined in this paper, we will hold discussions with NHSBT to agree the right level of communication to introduce these changes.

Six month evaluation of the pilot

16. In order to establish whether further changes are required at the six month stage, the Executive proposes to develop criteria for evaluating the pilot in advance of going live. This will also be discussed at the October meeting of the IAWG.

Next Steps

17. The Authority has previously agreed that a new system should go live at the start of 2012/13. As the proposals for the pilot are more straightforward than previously anticipated, we would expect that introducing these changes can be brought forward – possibly to the beginning of January 2012 – after the components have received Authority sign off.

Annex A – Draft Guidance to Transplant Units

Background

- The HTA has experienced an increase in the number of enquiries relating to how we assess “less traditional” relationships in directed donation cases.
- The HTA has a duty to assess all directed donation cases regardless of the relationship.
- Fundamentals of the assessment are the same i.e. understanding of risk and the absence of reward, duress and coercion. The Authority must be satisfied that these factors are not present.
- However, the assessment of such cases will be new ground and the Authority has concerns that certain relationships pose greater risk of reward changing hands and wish to mitigate this risk by scrutinising these cases rigorously.

Higher risk cases

The following cases will need to fulfil additional requirements:

- Cases where there is no evidence of direct contact between the donor and recipient which predates the recipient’s need for a transplant. This includes for instance:
 - Cases where first contact between the donor and recipient (either directly or through an intermediary) was for the purpose of organ donation.
 - Cases where a genetic, but non-qualifying relationship exists, and the donor and recipient have never met e.g. distant cousins.
- Cases where there is no genetic link between the donor and recipient but where the donor is in any way economically reliant on the recipient e.g. where the donor is an employee of the recipient.

The complexity of possible relationships is such that the HTA expect to develop these definitions as our experience increases. We would therefore expect to provide advice on the requirements for individual cases.

Proposed approach

- For these higher risk cases, we are intending to introduce additional requirements
 - An enhanced investigation process (e.g. psychological report exploring the motivation for directed donation).
 - The requirement for signed statements from the donor and recipient confirming that they understood the legal position in relation to reward.

Enhanced investigation

- Parallels with altruistic cases.
- Psychological assessment to focus on the donor's motivation for directed donation to explore the likelihood of reward being a factor.

Signed statements

- Rationale that these will act as a deterrent to illegal activity
- Statement requiring signature available as an annex.

Review

- HTA will review this approach as its experience in handling these cases develops, to assess the efficacy of this approach and the types of cases that require enhanced assessment.

Authority paper

Date	27 September 2011	Paper reference	HTA (49/11)
Agenda item	11	Author	Sarah-Jane Wakefield

Communications strategy - Update

Purpose of paper

1. On 22 March 2011, the Authority approved the new HTA Communications Strategy. It was agreed that the Executive would regularly report to the Authority on progress in delivering the strategy.
2. This paper provides the first *Communications strategy: evaluation report*, which we propose to provide to the Authority once every six months (twice a year). A draft of this report was discussed at the Communications Members' Group on 13 September and comments have been incorporated into this version. These include reducing the frequency of the report, adding useful new information, and making changes to the information we capture in the enquiries report.
3. A summary of the main activities is included on page 4 of the report.

Actions

4. The Authority is asked to comment on the *Communications strategy: evaluation report*, and notify us of any additional information they would like captured in these regular reports.
5. We will be reviewing our reporting of enquiries and ask the Authority to comment on what they would like to see in the enquiries report and to agree to the enquiries report forming part of the *Communications strategy: evaluation report* and reporting every six months.

Background

6. In order to ensure we are continually improving our communications activity (including enquiries), moving with the external environment, and meeting the needs of our stakeholders and the public, it is important that we undertake regular evaluation of our communications activity.
7. In addition, we want to report our progress against the HTA's Communications Strategy. The main aims of producing this evaluation report are:
 - **Accountability:** to raise awareness of the activities of communications, and to demonstrate the benefits of effective engagement.
 - **Continuous improvement:** to improve the effectiveness of our communications, by providing evidence of effective and ineffective activities; to gather examples of best practice to ensure continual improvement of the communications team; to share key metrics and provide evidence of progress against the HTA's communications strategy and strategic and business plans.
8. Carrying out effective evaluations takes time and effort. To ensure the worthwhile use of time and resources, and that the evaluation is effective, there are two key principles:
 - I. We are clear about what we want to achieve, and what success looks like at the beginning of projects and major activities. This will then inform our choice of evaluation methods.
 - II. Evaluation must inform future activity.
9. Our proposed strategy for evaluation and progress reporting will broadly fall into two main categories:
 - I. Ongoing metrics, which can be gathered and monitored, and used to analyse the effectiveness of the team, influence both day-to-day activities and long-term strategy.
 - II. Evaluation of specific communications strategies/case studies.

Communications strategy: evaluation report

10. This report, while extensive, is pulled together from existing statistics and information. Therefore, while resources are required to pull together this report,

they are not as extensive as they might be if the data were not already captured.

11. This report is the first of its kind and will act as a benchmark. Therefore, future reports will have more data analysis, trends and information because it will build up over time and cover a six month period.

12. In future, we will be reporting by exception. So if there was nothing new to report on a particular area then it would not be included. If there was something problematic, reputational, or high risk, or of a sensitive nature, then we would report to the Authority in a timely way, rather than waiting for the next report. This will keep the report as concise as possible.

Communications strategy: Evaluation report

September 2011

About this report

Purpose

This report forms the evaluation strand of the HTA's communications strategy. Its purpose is to provide regular and consistent metrics on the HTA's communications activity as well as more detailed case studies highlighting best practice. The key aims are:

1. **To provide a benchmark** for future evaluation, allowing progress against the Communications Strategy to be monitored.
2. **To ensure that** the work being done by Communications is shared across the team and the wider HTA.
3. **To share examples** of best practice and to allow lessons to be learned, so improvements can be feedback into our communications activity.

We will report on any problematic/reputational/high risk/sensitive areas on an exceptional basis as and when they occur, rather than waiting for the next evaluation report to the Authority.

Frequency

This report will be published **bi-monthly (once every two months) for HTA staff and communications**. Ideally within one week of the end of the two months being reported on.

A combined report covering a longer period of time, will be **presented to the Authority once every six months (twice a year)** starting on 27 September 2011, except where there needs to be exceptional reporting as outlined above.

Circulation

- **To Communications** (via email)
- **To HTA staff** (via the staff newsletter)
- **To Authority** (via Authority meeting papers)
- **Communications Members Group** (as discussion paper)

If you have any comments on this report, or suggestions for improvements for future versions, please contact Sarah-Jane Wakefield on extension 1958.

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[Please note: each of these sections would only appear in the report if we had something new to say or update the Authority on. If there was no change since the last report, then we would remove the section.]

Introduction

[Please note: This introduction would remain the same in each report, to provide context and as a reminder of our communications objectives].

HTA Communications strategy

The HTA Communications strategy was approved at the Authority meeting on 22 March 2011. With the interests of the public and those we regulate at the centre of our work we aim to maintain confidence by ensuring that human tissue is used safely and ethically and with proper consent. In order to maintain confidence especially in such a shifting external environment we need to ensure that high quality, timely and accurate information is widely available to those we regulate and the public, and that we get feedback from people affected by our regulation.

The following core messages describe the work of the Authority and represent the highest level key messages which the Authority will be seeking to communicate through this strategy.

- The reasons the HTA were set up have not gone away.
- Human tissue and organs must continue to be used safely, ethically and with proper consent.
- Consent is the golden thread that runs through the Human Tissue Act.
- The HTA's functions must be kept together – *dividing would be diluting**.
- We aim to build public confidence in what we do, not necessarily in who we are.
- Increased public confidence may increase willingness to donate tissue and organs, so supporting healthcare outcomes.

Communications objectives

The communications objectives were agreed by the Communications Members Group meeting on 25 January 2011.

- Objective A: Building public confidence.
- Objective B: Engaging with professionals.
- Objective C: Influencing the ALB process to *protect our functions**.
- Objective D: Using internal communications to support staff.

**Please note we will be revisiting this wording in the communications strategy, as it is not felt on reflection that this is quite the right wording.*

Summary

[This would be a summary of the key highlights from the report, changes and learning from the previous report – so it can be seen at a glance what has been achieved over the previous two months.]

This is the first *Communications strategy: evaluation report* and covers the period July-August 2011. This has been a busy couple of months for communications activity, and a period of increased interest in the HTA. Work has continued to raise the HTA's profile and reputation with stakeholders and the public and there has been real progress in implementing of the HTA's communications strategy.

The last two months have seen an **increased amount of media coverage and interest** as a result of our own proactive media work, but also debate and discussion around a couple of key topics: presumed consent in Wales, directed donations and payment for organs. These discussions have provided us with a real opportunity to explain more about what the HTA does, our role in these areas and our position on these debates, raising our profile and reputation.

July and August saw the start of the **HTA's public outreach project**, to seek the views of the public about our work, from a user perspective. The project will allow us to assess the level of confidence the public have in the consent processes that allow for the ethical use of tissues and organs, and the regulatory system that governs them.

The number of **visitors to our website** continued to increase with people looking for information on our work, the Human Tissue Act, Codes of Practice and body donation. These increased numbers support our plans to develop an HTA digital strategy, to ensure we are making the best use of our digital channels, providing the information our audiences need and in an accessible and easy way.

The **Annual Review of the Year 2011** report proved popular with our stakeholders and the public with the largest number of downloads on our website and the event and debate we held in July was a huge success, with really positive feedback. The budget was reduced by £21,000 compared with 2010.

Finally, we have listened to the views, thoughts and feedback from colleagues across the HTA and **revisited our internal communications** strategy and mechanisms to ensure they continue to support staff and their needs.

More detail on all these areas, the work that has taken place, and the statistics/evidence on our recent communications activity can be found in the following pages.

Media activity

Over the last two months, there has been an increased amount of media coverage and interest in the HTA following a Serious Untoward Incident (SUI), the debate on payment for organs, the story of the Flood Sisters and a directed donation case, and the issue of presumed consent in Wales.

Proactive media work

During July and August the HTA issued three press releases and an event summary to the media. These were:

- Findings from the post mortem sector audit report.
- Announcement of new Chief Executive.
- Statement on ten year anniversary of retained organs, fetuses and tissue samples in Birmingham.
- Summary of the Annual Review of the Year event and debate.
- During this period we also issued an official statement on donation and remote relationships, on request.

As a result some of the media coverage included an article in the Sunday Times “*Mother finds new kidney on the net*”, which looked at directed donation between people who do not have a genetic or established emotional relationship. In relation to the same story the HTA featured on [BBC Radio Five Live](#) (at 45 minutes, 1hr and 23 and 2hrs 57 minutes in); the [Daily Telegraph](#); [News Point \(SA\)](#), the [Deccan Chronicle](#), [ITV regional news](#), the [Today programme](#) (1hr 45 mins in), [BBC online](#) and [BBC London Breakfast at 2hrs and 35 minutes](#). Vicky Marshment was also interviewed on [BBC London drive time](#) <http://www.bbc.co.uk/iplayer/console/p00jqprl>.

Media enquiries

During July/August we received 20 enquiries from the media – these covered enquiries about altruistic donations (1); anatomy (1); payment for organs (4); the police audit (2); pooled donation (1); presumed consent (3); and transplants and remote relationships (7).

Coverage linked to the work of the HTA

Some of the coverage over the last two months that made reference to the HTA included: a post mortem story on [BBC London](#), in [The Evening Standard](#), [The Daily Mail](#) and [The Metro](#). The HTA was also referenced by the [BBC](#), [The Independent](#), [The Daily Mail](#) and The Metro in coverage of a police audit. [The Guardian](#) highlighted the HTA in a feature on body donation. [Wired](#) cited the HTA in a public display feature. The HTA was mentioned in media coverage about a proposal for payment for living kidney donors on the [BBC](#), in [The Guardian](#), [walesonline.co.uk](#) and [The Scotsman](#). BBC London News contacted us about a mix up of bodies at Hammersmith Hospital, which followed our release of SUI's to a journalist under FOI.

Stakeholder/public activity

July and August saw the start of the HTA's public outreach project, previously approved by the Authority, which is a main feature of the Communications Strategy and the HTA's additional focus on the public. In addition, we continued to monitor the Public Bodies Bill through Parliament and kept stakeholders updated on our work through the e-newsletter.

The Public Outreach project

The purpose of this project is to seek the views of the public about our work, from a user perspective. It will allow us to assess the level of confidence the public have in the consent processes that allow for the ethical use of tissues and organs, and the regulatory system that governs them. In particular it will allow us to:

- Explore any negative/hesitant reactions to the giving of consent to determine whether they emanate from concerns/mistrust in the 'system' or whether the hesitancy lies elsewhere.
- Where confidence in the system is apparent, explore the reasons why.
- Compile a library of human interest stories for use across a multitude of communications channels.
- Alert the HTA to any trends or views we might want to explore further on completion of this project.
- Gather information which could be useful to inform discussions with professionals, providing a balance to their views and policy development.

The scoping of this project has now taken place and a project plan has been developed and approved by SMT. The first interviews with the public have started to take place and this will continue over the next few weeks.

Public Bodies Bill

On 12 July, the Public Bodies Bill (PBB) had its second reading in the House of Commons. The debate focused mainly on a number of organisations affected by the Bill including the role of Chief Coroner; the Youth Justice Board; the Equality and Human Rights Commission; the Agricultural Wages Board; S4C (Welsh Language channel) and the Regional Development Agencies. There was no mention of the HTA or our partner organisations. There was a clear theme across all of the debate, which was more about the cost of these reforms and the people affected by them, what it meant for the workforce and morale.

The Bill is currently going through the Public Bill Committee stages.

E-newsletter

The number of subscribers to the HTA e-newsletter is now at 7,000, this has increased from 6,000 in July last year.

Digital statistics

The HTA continues to provide information for the public and stakeholders on our website, and is working to continually make improvements to the website including content, structure, and sign-posting. The HTA recently launched a Twitter and Facebook Page, and we are slowly starting to build up our use of these channels (which will form part of the digital strategy).

Headline statistics for the entire HTA website

	July 2011	August 2011	Change July-Aug
Visits	35,740	41,084	5,344 ↑ 15%
Page views	125,312	157,237	31,925 ↑ 25%
Twitter followers	N/A	35	N/A
Facebook followers	42	43	1 ↑ 2%

Twitter is a social media channel that is instant and timely, so it allows us to get information out quickly and for people to receive it instantly. An example of how we have used it is for the Annual Review of the Year event when we tweeted the event as it happened, to issue press releases for journalists; and to issue statements. It is also a useful tool for engaging in dialogue with our audiences and directing them to our website. Currently **our Twitter followers** range from health reporters; charities; partner organisations/stakeholders e.g. MHRA, Royal College of Surgeons; staff (3); organisations in research particularly cells; donors; interested members of the public.

Facebook, is more useful for providing longer-term static information, videos, pictures, but again would be potentially useful for a dialogue with our audiences and directing people back to our website. Currently our Facebook followers: charities; medical associations; royal colleges; members of the public; staff (12).

Whilst the HTA should have a social media presence as it allows people we do not normally reach a route to be aware of our work. There is potential for the HTA in using these channels, but this must be balanced out with our objectives, establishing what a meaningful return would be and best use of resources. This will be covered in more detail in the digital strategy currently being developed.

Top search topic

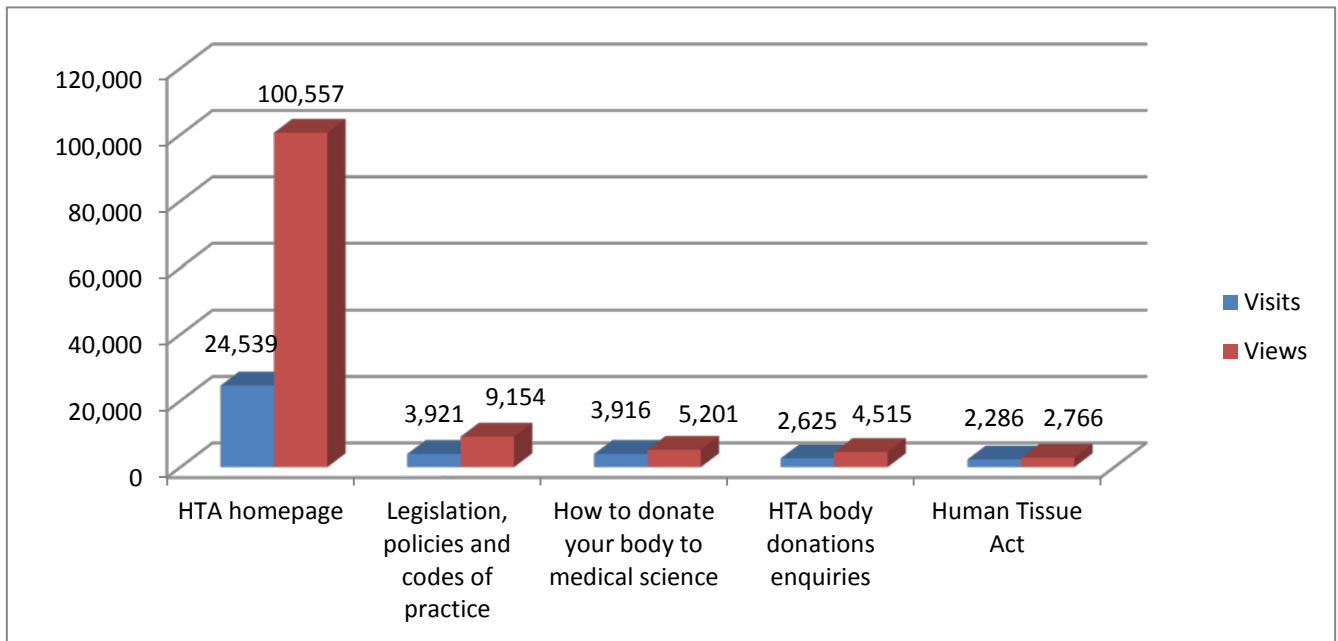
This provides the top phrases used in search engines, which results in people visiting the HTA website during July and August.

1. HTA
2. Human Tissue Authority

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

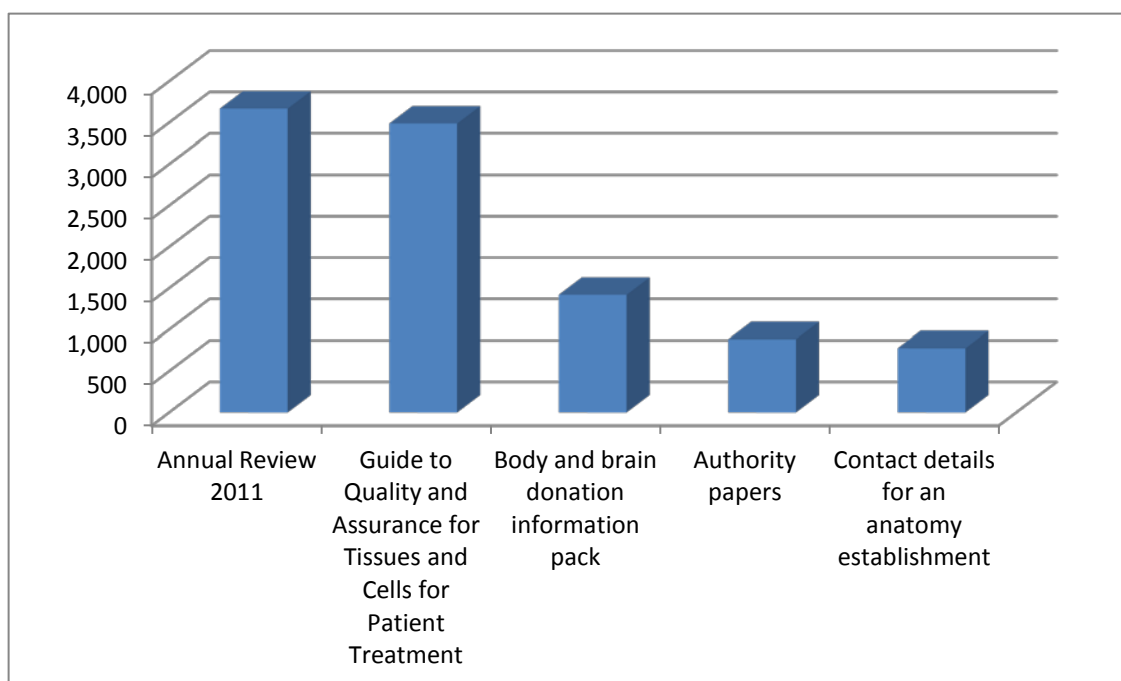
3. Human Tissue Act
4. Blood
5. Codes of Practice

Top pages

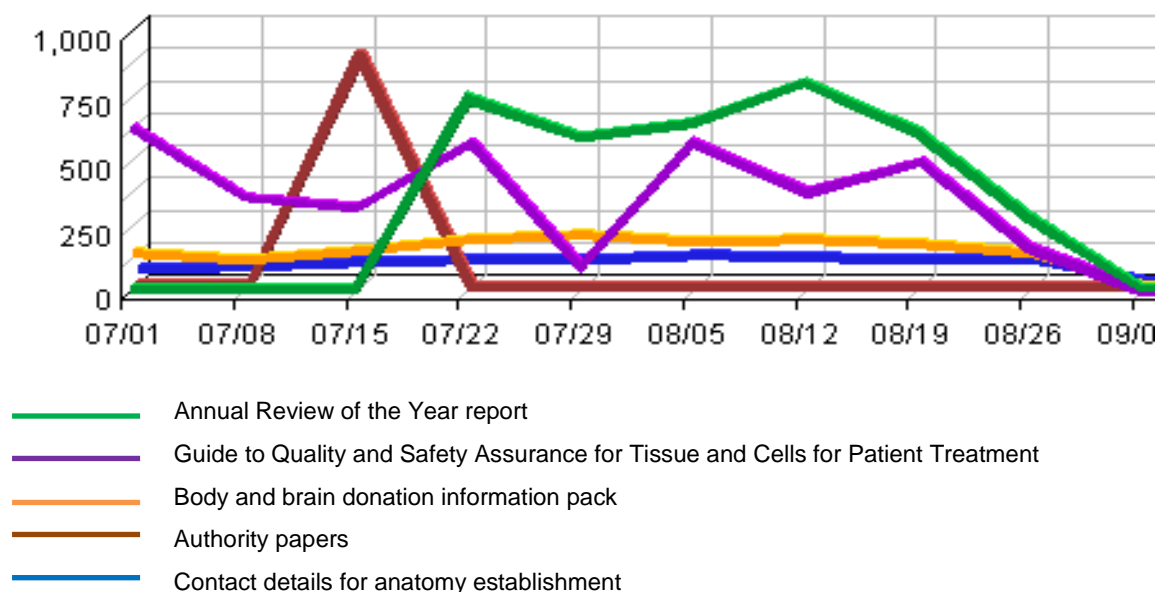


**HTA body donations enquiries relates to the 'find your nearest medical school' page*

Most downloaded files: July and August



Most downloaded files - peaks



On the 26 July we issued a news item on the website, to announce the publication of our Annual Review of the Year report, and issued a letter with a link to the report to all the original stakeholders that were invited to the event. This would explain the peak in downloads between 26 July and 12 August.

There was the Authority meeting on the 26 July, which was held in public and communicated to our stakeholders via the e-newsletter, this would explain the peak in Authority papers prior to 26 July.

Top referring websites

The top websites that people came to the HTA website from in July and August, were www.google.com and www.bing.com. This would be expected, but after search engines other websites for these two months were 'If I should die' website; Royal College of Surgeons of England; Government jobs direct website and the NHSBT Organ Donation website.

Publishing statistics

The HTA does not generally produce a large number of publications. There are a number of annual publications including the Annual Report and Accounts and Annual Review report and more regular publications tend to be inspection reports.

On the whole the majority of publications are published online and so do not incur any additional costs for design, printing or distribution. For the first time this year, we made the decision to not print the Annual Review publication, but to make it available online only. The exception was 100 copies for the Annual Review of the Year event, which were printed in house at no extra cost.

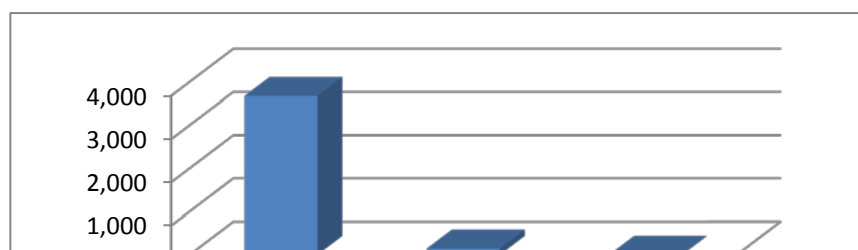
- The only costs incurred on publications during June and August was £4,805 for the design, layout and photography for the Annual Review of the Year publication.
- On 7 July 2011, we published the findings from our Post Mortem Sector Audit and this report was produced in-house and again published online only.
- The HTA Annual Report and Accounts 2010/11 was laid in the house on 30 June, and a copies were printed to ensure we met our Parliamentary requirements.

Summary

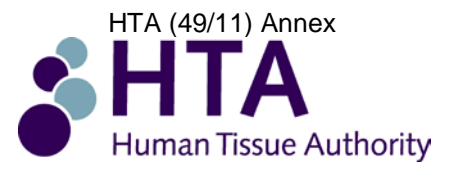
	Documents produced	Printed copies	Additional costs (£)	Average downloads
Annual publications	2	100	4,805	1,907 (3,669/145)
Inspection reports	0	0	0	
Codes of practice	n/a	n/a	0	-
Other HTA documents	1	n/a	0	n/a*
Total	3	100	4,805	-
Change on previous report	n/a	n/a	n/a	

*The PM sector report does not make the top 200 downloads during this period, as the download amount is too small. However, this was sent directly by email to DIs.

Publications in July/August 2011 – web downloads



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Enquiries report

The Authority received the last enquiries report at their June meeting. We would like to start providing the enquiries report as part of the *Communications strategy: evaluation report* as there will be links and overlap in the analysis e.g. a decrease in enquiries for a particular area may be the result of additional communications activity or information we have put on the website. Bringing the two together therefore will provide richer evidence and information for analysis and identifying trends and themes.

We are currently undertaking a project to review the management and reporting of enquiries. This will include reviewing current processes for dealing with enquiries; establish where improvements and efficiencies can be made and work with colleagues to implement those improvements. In addition we will be establishing an enquiries 'champion' role responsible for providing ongoing oversight. This 'champion' would bring together the different parts of the organisation dealing with enquiries, working with colleagues to drive improvements and undertake the system-wide analysis and reporting.

As part of this project, we will be reviewing our reporting of enquiries and would therefore like your comments on what you would like to see in the enquiries report and what information would be useful.

Discussions at the communications members group propose that the report will focus on:

- How many enquiries we have received; are they answered on time; how many aren't and for those that aren't what are they about.
- The context, any political context particularly in relation to FOI's.
- What are the difficult enquiries, how are we dealing with them.
- Reporting on anything that falls out of the day-to-day.
- If there has been changes e.g. the number of enquiries dropping why is that.
- When do enquiries become complaints and what are we doing about those.
- The impact of difficult enquiries on staff resources and time.
- We have also implemented the change to 'referral' rather than complaint regarding establishments as requested at the last Authority meeting and will include this information in the report.

Communications resources

Sarah-Jane Wakefield, the new Head of Communications started on 13 June 2011, as reported to the last Authority meeting. Sara Coakley, is now dedicated to the Public Outreach Project until November. In the meantime her media and public affairs duties are being picked up by the rest of the team, but this has meant that work has been prioritised, activities have been rescheduled to ensure they are still undertaken but in a more manageable time scale and there is not such a demand on public affairs at the moment.

We have a new pool of assistants, who are providing administrative support to the Communications team.

Internal communications

SMT approved a revised internal communications strategy on Thursday 1 September, which builds on the original internal communications strategy 2009–2010 for the HTA. Since the implementation of the 2009 internal communications strategy the HTA has undergone a number of changes including the announcement of the arms-length bodies review, two new Chief Executives, turnover of the Director of Regulations, a reduction in staff numbers, and a move towards a new focus on the public. As a result, internal communications needs to continue to develop to meet the changing needs of the organisation.

In order to ensure HTA internal communications remains effective, efficient and continues to make best use of the resources available, a revised strategy has been drawn up to continue to support staff. This strategy has been revised using the feedback and comments received by colleagues and through the HTA staff forum.

Internal communications has continued to improve and there is much about our current internal communications that is effective and works well for staff. Therefore, we are not suggesting overhauling everything or starting from scratch, but just continuing to evolve and improve the HTA's internal communications.

What's changing?

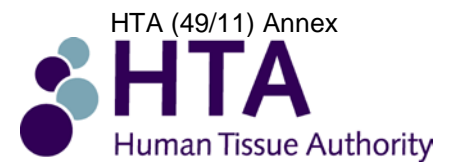
- A revised set of **objectives and guiding principles** on which all internal communications will be based is being introduced.
- Communication will happen in a more **coordinated, and timely manner**.
- The way we write messages will change to increase **consistency of content, house style and tone, so all non urgent All-Staff emails/news items should come through communications for checking**.
- We will make **improvements to some of our channels**, such as staff meetings, internal newsletter and IMPACT.
- Reduce the **over-reliance and use of all HTA staff emails** to reduce email traffic, clutter and un co-ordinated communications.
- Updated and revised **communications tools/guidance** to assist staff in their work.
- Review and relaunch of the **annual staff survey**.
- Improved **consultation and feedback** processes and mechanisms.

What's new?

- A more interactive and engaging approach to communications, with the introduction of **digital media** including a new CEO blog.
- Investigating a '**corporate**' **objective** for all Directors and Heads.
- **A new weekly cascade**, which involves a weekly internal newsletter to all staff and a separate morning/breakfast briefing for Heads with the CEO on key corporate matters. Heads are then expected to cascade this information, in a timely manner, to their teams during team meetings and/or one-to-ones.

We are also exploring ways in which we can capture regular feedback on internal communications from staff outside of the annual staff survey. We have just undertaken this years annual staff survey, and the results of that will provide us with a benchmark for staff

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views and feedback.

Forward look

This section will provide a brief look at what communications activity we are expecting to take place over the next two months.

Stakeholder activity/public

We will be continuing the interviews as part of the public outreach project and will be preparing for the Department of Health's consultation on the options for transferring the functions of the HTA. As part of our stakeholder management a series of planned introductory meetings will be taking place with our key stakeholders and Alan Clamp, in his new role as Chief Executive.

We will be issuing our consultation on the ODD Directions in line with Department of Health's consultation on the regulations. This will be a direct communication to stakeholders, supported by a piece on the website, in our newsletter and regular reminders using Twitter and Facebook.

Digital communciations

Over the coming few months we will be developing a digital strategy for the HTA, which will provide a vision and strategic plan for how we develop our digital channels in the most effective and efficient way.

Publications

There are currently no forthcoming publications planned (except for regular inspection reports). We will however be producing information for the public on the post mortem process and legal framework relating to human tissue.

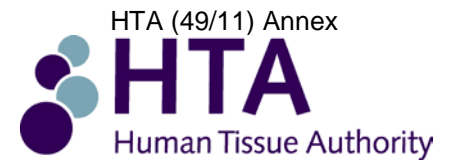
Enquiries

We will be undertaking a project to review the management and reporting of enquiries. This will include reviewing current processes for dealing with enquiries; establish where improvements and efficiencies can be made and work with colleagues to implement those improvements. In addition we will be establishing an enquiries 'champion' role responsible for providing ongoing oversight. This 'champion' would bring together the different parts of the organisation dealing with enquiries, working with colleagues to drive improvements and undertake the system-wide analysis and reporting.

Internal communications

We will be launching the new elements of the internal communications strategy, as mentioned above, and will also be issuing the staff survey, analysing the results and developing appropriate actions. The internal audit of the HTA's major incident reporting has been underway and aims to deliver a review of arrangements relating to major incident reporting to

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inform our understanding of key risk management and internal control arrangements at the HTA. It will be reporting to the Audit Committee in November.

Case study: Annual Review 2011

Introduction

As a result of feedback from previous years and a drive to save money, it was decided this year that the Annual Review of the Year event would be an afternoon rather than whole day event, and would be held on the same day as the Authority public meeting.

There were 41 people at the Authority public meeting in the morning and 62 at the Annual Review of the Year event in the afternoon at the Wellcome Trust in London (73 people had registered) and this compares with 76 in 2010. The delegates were from a range of professional stakeholder and public groups.

Attendees were provided with an evaluation form, and prompted to complete it on a number of occasions throughout the day. We received 22 completed evaluation forms, but HTA staff also received ad hoc feedback during the day.

The aim of this report is to provide a summary of the feedback we received from delegates, and to identify what further improvements can be made for future events.

Summary of key findings

From the evaluation forms completed the key findings are as follows:

- All of the respondents felt that events such as the review of the year are a good way to engage with stakeholders; 59% strongly agreed and 41% agreed.
- The afternoon debate on organ donation was well received by attendees with 96% either strongly agreeing or agreeing with the statement: *the debate on organ donation was interesting and engaging.*
- All the presentations scored highly with the majority of respondents agreeing that the presentations *were useful and informative.* The presentation on the context for the organ donation debate was the most highly received with 91% either strongly agreeing or agreeing that the *presentation provided useful background to the debate.*
- 86% enjoyed attending the event, with 14% responding neutral. 91% of respondents found the venue to be suitable for the event.

Delegates were asked to 'tick' the relevant response for each statement or question. A sliding scale was provided: strongly agree, agree, neutral, disagree or strongly disagree. The attached chart shows a breakdown of the percentage of response for each statement.

Open comments

In addition to the statements above, the respondents were asked to comment on their response to: *the debate on organ donation was interesting and engaging*. The comments received were consistent and highlighted:

- The excellent mix/balance of speakers;
- The different points of view, which were useful and informative;
- The debate was thought provoking and interesting;
- The debate was informative and having personal presentations made all the difference.

When asked *the best thing about the event*, respondents were once again consistent in their responses and highlighted:

- Meeting other people;
- Central location;
- Content – good debate, informal and friendly;
- The event was well managed, the materials very professional and speakers were excellent;
- Balanced programme;
- Summary of ALB situation.

When asked *what you would have improved about the event*, respondents raised:

- The audio in the morning (although only two respondents raised this in their evaluation);
- Longer Q&A session;
- The use of anonymous voting buttons would have allowed more truthful views to be expressed;
- More extreme views on practice of rewards.

Annual review publication

For the first time this year, we also asked respondents what they thought of the Annual Review publication. The comments received were very positive and included: extremely professional; well presented; concise and clear and very succinct. There was a suggestion to include a synopsis of one or two of the interesting cases handled during the year and one respondent thought that all the colour photos should be removed.

Resources

It was a priority this year to make efficiencies and ensure value for money while still ensuring an engaging and effective event.

Last year the cost of the Annual Review of the Year event (including publication of the Annual Review document) was **£29,061**. These costs included venue hire, voting buttons, video and transcription, photography, and printing and design of the publication.

This year the event cost under **£8,000** (including the cost of the morning Authority meeting) with savings made on the venue and location, not using the voting buttons, publishing the Annual Review online only, and more focused use of video.

Comparison

It is important to contextualise these results with a comparison with last year's review of the year event. This will highlight improvements we made in light of the feedback received previously and any areas that are still in need of improvement.

The table illustrates four comparable answers received from the sliding scale questions of the evaluation report.

Statement	2010	2011
<i>I think events like this are a good way of engaging with people affected by HTA regulation</i>	52% strongly agree 42% agree 2% disagree 4% no response	59% strongly agree 41% agree 0% neutral
<i>The presentation reporting on the HTA's work over the past year was useful and informative</i>	25% strongly agree 67% agree 6% neutral 2% no response	18% strongly agree 64% agree 18% neutral
<i>The debate session (2010: payment for organ donation / 2011: relationship and risks of organ donation) was interesting and engaging</i>	71% strongly agree 21% agree 4% neutral 2% no response	41% strong agree 55% agree 5% neutral
<i>The venue was suitable for the event (in 2010 the venue was the Law Society and in 2011 the Wellcome Trust)</i>	52% strongly agree 42% agree 4% neutral 2% no response	23% strongly agree 68% agree 9% neutral

In comparison to last year's event, these results would indicate that there were some reservations about the subject matter of the presentations this year, as there was not as many 'strong agreements'. Therefore, there may be a need to ensure the presentations provide new information rather than reviewing activities and reflect the background/context of those attending e.g. if they are mostly from licensed establishments then they will already know about how we regulate.

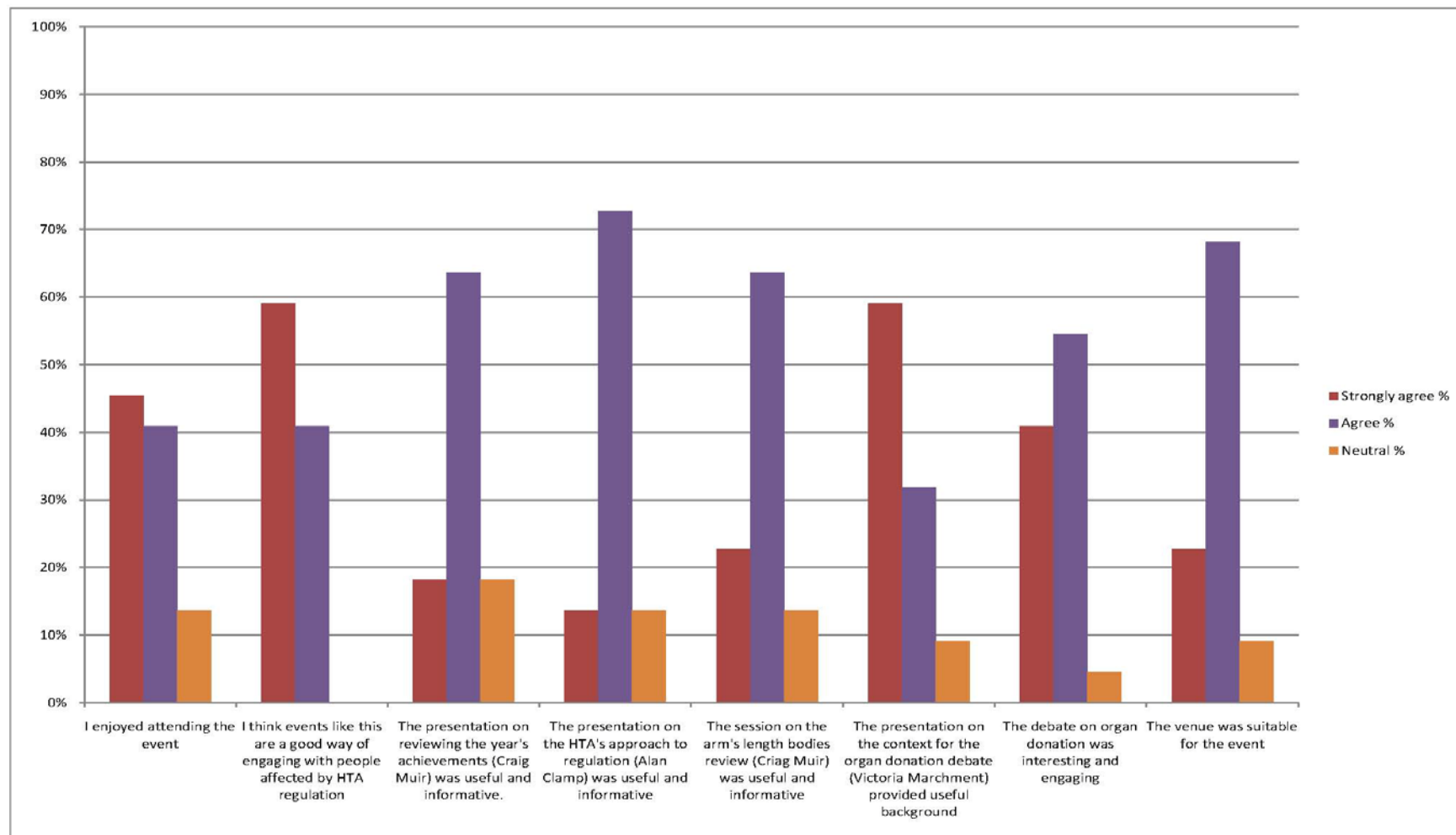
Recommendations for future events

The evaluation received from the event was all very positive and demonstrates that the event was a real success. However, there are always improvements that can be made for future events. Our initial recommendations for consideration when planning any future HTA events are:

- Carefully consider the timing of the event and the Authority meeting if tied together – as this was during recess and the school holidays it meant it was difficult to find speakers and a Chair who were available. This may also have an impact on attendee numbers.
- Reflect on the nature of the presentations and the formula of presentations used for these events to ensure we are providing 'new' and interesting information for those attending.
- Ensure enough time is allowed from Q&A at the end of sessions.
- Delegate packs should be made available for staff, Authority members and speakers to ensure they have all the relevant information including delegate lists etc.
- Carefully consider venue for future meetings and room configuration to ensure there are not any problems with sound. This should include briefing speakers on using the microphones.
- Ensure a technician is available at all times, in case of any difficulties.
- Provide water in meeting room for delegates, particularly during long sessions when there is not a break.

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

HTA (49/11) Annex



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

Authority paper

Date	13 September 2011	Paper reference	HTA (50/11)
Agenda item	12	Author	Sue Martin

Financial report August 2011

Introduction

1. This paper provides a report of the HTA's financial position as at 31 August 2011, five months into the business year.
2. The report provides commentary on the following areas:
 - budget constraints
 - overview of financial position to 31 August 2011
 - income and expenditure variances
 - forecast outturn
 - other key performance indicators
 - financial risks

Action

3. The Authority is asked to note the financial position as at 31 August 2011.

Budget constraints

4. The Department of Health (DH) has carried out a review of the controls over expenditure put in place in May 2010 with a view to tailoring them to Arm's Length Bodies (ALB) with particular circumstances and streamlining their operation whilst retaining a level of assurance required by key stakeholders. While some thresholds have been increased, the review outcome has no material effect on the HTA and its operations. We are still subject to business case approval for spend on professional services.

Overview of financial position at 31 August 2011

5. **Annex A** shows the summarised financial position for the year to 31 August 2011. At that date, there was an overall under-spend on revenue expenditure of **£228k** and **£108k** more income in total than anticipated. Together these resulted in **£336k** more surplus than expected.

Income – variances to 31 August 2011

6. **Annex B** provides a more detailed breakdown of income generated to 31 August 2011. In the five months, compared to budget, there is more income than expected. Now that the July invoices have been issued, and income from the entire human application sector is known, there is **£108k** more than expected. This has reduced from last month because of a credit due to an establishment in the tissue for treatment (human application) sector.
7. Half of the original allocation of revenue Grant-in-Aid has been drawn down from DH. The remainder is expected to be drawn down by February 2012. The additional revenue funding (c£113k) available for the Organ Donation Directive is not shown in the report yet – this will be included when we draw it down later in the year.

Expenditure – variances to 31 August 2011

8. **Annex C** shows expenditure as at 31 August 2011 for staff and non-staff costs. To date, there is an overall under-spend of **£228k**.
9. The under-spend on staff costs of **£137k** is the result of unfilled posts. Added to this is a net under-spend on non-staff costs of **£91k**. Spend on training and recruitment and IT & telecommunications will take place later than expected. Capital charges are different from our assumptions and will remain so to the end of the financial year.
10. The details of variances are summarised below:

Expenditure Variances		
	£	Notes
Staff costs	136,793	Vacant posts which are under review.
Non staff costs	91,001	This variance is analysed in greater detail in the lines below.
Training & Recruitment	24,802	Activity has not happened as early in the year as expected.
IT & Telecommunications	15,090	IT development has not happened as early as expected.
Legal	(13,774) ¹	Additional cost because of advice required,

		primarily for the Employment Tribunal.
Accommodation	11,387	Building Services (facilities) costs have been less than expected to date.
Capital charges	42,336	Changes in accounting treatment of assets.
Other variances	11,160	Reduction in spend on Staff Benefits within Other Costs. Imposed controls reducing spend on Consultancy.

1 () denotes an over-spend

11. **Annex D** provides an analysis of expenditure by Directorate. All Directorates are currently under-spending against budget for the reasons above. The small over-spend by the HTA Board is due to profile of the venue hire budget and is expected to be absorbed later in the year.

Forecast outturn

12. There have been no significant changes to the forecast outturn. In October, after six months, a more detailed review will be undertaken with Directors.

13. The forecast outturn at this stage is at least £406k less expenditure than expected and this is likely to increase later in the year. We now have £108k more income than expected so we report a forecast surplus of **£508k** at this stage. Surplus licence fees would be credited to establishments later in the year when the amount is more certain.

Other key performance indicators

Reserves

14. Total reserves at the end of August are £3.8m and our cash balance is £2.7m.

Debtors

15. As at 31 August our licence fee gross debtor balance was **£444k**. This includes debts being settled from last year and debts relating to invoices issued since April. Fees are outstanding from a total of 52 establishments. **61%** is due from NHS bodies, **39%** from private sector bodies.

16. There are 5 establishments who have not paid the 2010/11 fee invoices (totalling **£38k**) and continue to cause concern. Legal action will be taken during September.

17. There are 7 establishments with outstanding balances from the April 2011 invoices (totalling **£73k**). 5 establishments have yet to pay and 2 are paying in instalments.

Prompt payment

18. For the five months ended 31 August, **83%** of invoices were paid within 5 days and **98%** within 10 days. Average payment time was **2.7 days**.

Financial risks

19. Below is a table of the risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high level strategic risks that SMT have identified and are managing. The risk of less fee income than expected due to different establishment profiles has now passed.

Risk	Link to the HTA's strategic risks	Mitigating actions and controls
A significant under-spend leading to a loss of stakeholder confidence in HTA's ability to manage resources effectively.	Inadequate relationship management	Identification of the likely outturn as early as possible. Credit of unused licence fees to establishments.
Lack of prompt payment by licence fee payers affects cash flow and operations generally adversely.	Insufficient financial resources	Revenue collection will be closely monitored and the HTA's credit control and debt collection procedures used to pursue and recover all late payments.
The HTA is required to undertake additional functions or activities not planned or costed within the approved budget.	Insufficient financial resources Failure to manage change Inability to carry out its statutory remit	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.

Human Tissue Authority

Summary - Income & Expenditure

Annex A

For the Five Months Ending 31 August 2011

Year to Date			FORECAST			
Actuals	Budget	Variance	Outturn	Budget	Variance	
£	£	£	£	£	£	%

INCOME & EXPENDITURE SUMMARY							
Income	(2,285,353)	(2,177,025)	(108,328)	(5,185,703)	(5,083,000)	(102,703)	2.02%
Less:							
Expenditure	1,781,412	2,009,207	(227,794)	4,632,110	5,037,874	(405,764)	-8.05%
Gross (surplus)/deficit of income over expenditure	(503,941)	(167,818)	(336,123)	(553,593)	(45,126)	(508,468)	
Net (surplus)/deficit of income over expenditure	(503,941)	(167,818)	(336,123)	(553,593)	(45,126)	(508,468)	

Human Tissue Authority

Member Income Summary

Annex B

For the Five Months Ending 31 August 2011

	Year to Date			FORECAST			
	Actuals £	Budget £	Variance £	Outturn £	Budget £	Variance £	%
Grant In Aid							
GIA	477,000	476,775	225	954,000	954,000	0	0.00%
Sub-Total	477,000	476,775	225	954,000	954,000	0	0.00%
Licence Fees							
Anatomy	0	0	0	141,000	141,000	0	0.00%
Post Mortem	1,200	0	1,200	1,596,000	1,596,000	0	0.00%
Public Display	0	0	0	19,000	19,000	0	0.00%
Research	4,200	0	4,200	672,000	672,000	0	0.00%
Human application	1,702,733	1,600,000	102,733	1,702,733	1,600,000	102,733	6.42%
Sub-Total	1,708,133	1,600,000	108,133	4,130,733	4,028,000	102,733	2.55%
Other							
Other income	0	29	(29)	750	779	(29)	-3.72%
Scottish & N. Ireland Execs. & Welsh Assembly	100,221	100,221	(0)	100,221	100,221	(0)	0.00%
Sub-Total	100,221	100,250	(29)	100,971	101,000	(29)	-0.03%
Total Income	2,285,353	2,177,025	108,328	5,185,703	5,083,000	102,703	2.02%

Human Tissue Authority

Summary - Expenditure

Annex C

For the Five Months Ending 31 August 2011

Year to Date			FORECAST			
Actuals	Budget	Variance	Outturn	Budget	Variance	
£	£	£	£	£	£	%

EXPENDITURE SUMMARY							
Staff Costs	1,115,799	1,252,592	(136,793)	2,648,538	3,000,017	(351,479)	-11.72%
Non Staff Costs	665,614	756,615	(91,001)	1,983,572	2,037,857	(54,285)	-2.66%
Gross Costs before Exceptional Items	1,781,412	2,009,207	(227,794)	4,632,110	5,037,874	(405,764)	-8.05%
Total Expenditure	1,781,412	2,009,207	(227,794)	4,632,110	5,037,874	(405,764)	-8.05%
	=====	=====	=====	=====	=====	=====	=====

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Human Tissue Authority

Directorate Summary

Annex D

For the Five Months Ending 31 August 2011

	Year to Date				FORECAST			
	Actuals £	Budget £	Variance £	%	Outturn £	Budget £	Variance £	%
Communications and Public Affairs	107,019	115,148	(8,129)	-7.06%	281,107	284,884	(3,777)	-1.33%
Regulation	583,750	670,628	(86,879)	-12.95%	1,384,975	1,635,096	(250,121)	-15.30%
Strategy and Quality	100,852	119,913	(19,061)	-15.90%	276,128	298,270	(22,142)	-7.42%
HTA Board	69,521	68,525	997	1.45%	161,685	162,859	(1,174)	-0.72%
Resources	728,855	810,708	(81,853)	-10.10%	1,916,063	2,028,901	(112,839)	-5.56%
Chief Executive's Office	191,416	224,285	(32,869)	-14.65%	612,153	627,864	(15,711)	-2.50%
Subtotal	1,781,412	2,009,207	(227,794)	-11.34%	4,632,110	5,037,874	(405,764)	-8.05%
Total Directorate(s) Expenditure	1,781,412	2,009,207	(227,794)	-11.34%	4,632,110	5,037,874	(405,764)	-8.05%

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Authority paper

Date	27 September 2011	Paper reference	HTA (51/11)
Agenda item	13	Author	Allan Marriott Smith

Strategic Performance Review – August 2011

Purpose of paper

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

Action

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

Background

3. The Authority has agreed to monitor a set of KPIs that demonstrate whether the HTA's strategic aims are being delivered.

Progress in August 2011

Regulation

3. KPIs 1.7 and 1.13, which require 90% of **Corrective and Preventative Actions** (CAPAs) to be completed within the agreed deadline, were missed in August.
4. For the human application sector (KPI 1.7), 57% (four out of seven) CAPAs were completed within agreed timescales. For establishments licensed under the Act (KPI 1.13), this figure was 0% (zero out of one). However, it should be noted that stringent criteria are applied when assessing these KPIs and only written confirmation that a CAPA plan has been completed will trigger HTA sign-off.

5. Closer analysis of the human application figures, which comprise three uncompleted CAPAs relating to two establishments, reveals a more balanced situation. Two of the outstanding CAPAs are planned to be confirmed during a site-visit inspection in late September and, in the case of the remaining CAPA, the responsible Regulation Manager needed to request further information in order to assess whether the CAPA had been satisfactorily completed. For establishments licensed under the Act, the single outstanding CAPA had been orally confirmed as completed, but the Regulation Manager was awaiting written confirmation.

Strategy and Quality

6. All KPIs are on target.

Communications and Public Affairs

7. KPI is on target.

Resources

8. All KPIs are on target.

CEO

9. The ***vacancy rate*** (KPI 3.1) was judged green with an outturn of 4% against a target rate of 5%. This rate has been calculated by taking the complement of staff that has been agreed by SMT as of the end of August (46) and the number of vacancies with are still in the process of being recruited (1 Regulation Manager and the Quality and Policy Manager). The Regulation Directorate has undertaken an exercise to identify the steady state target level for staffing, and the complement is likely to change as a result of this.
10. KPI 3.2 ***relating to attrition*** is judged amber. During August one Regulation Manager left the HTA (Melanie Reid). Two further Regulation Managers will leave during September and October.
11. In order to better understand the issues underlying staff turnover, the Executive has recently undertaken an analysis of exit interviews and leaver data for the last three years. A summary of the key findings is attached in the Annex.

Annex – HTA Leaver Analysis

Purpose of paper

1. To provide a summary of the exit interview and leaver data from the last three years, September 2008 to June 2011.

Overview of data

2. 34 permanent staff and fixed term contractors left between September 2008 and June 2011. The number of leavers in each of the smaller directorates, Communications and Public Affairs, Strategy and Quality, Resources and CEO's office is approximately 100% turnover in the last 3 years. In the Regulation directorate the turnover has been about 50%.
3. Out of the 34 leavers, there were 5 non-voluntary terminations which included dismissal, dismissal during probation and end of fixed term contract. All the remaining 29 leavers were voluntary resignations and retirements. Of the 29 leavers that left voluntarily, 6 of those had less than 12 months service. This statistic is slightly deceptive as 3 of those people had worked for the HTA either as a temp or through an SLA before being made permanent. This means that the actual length of service was longer than 12 months, just not in a permanent capacity for those 3 people.
4. The average length of service of all of the permanent leavers between September 2008 and June 2011 is 26 months.
5. The exit interview data includes 27 people who had an exit interview or filled out the standard exit interview questionnaire, most of them permanent staff but with some temporary staff and contractors.

Summary response of exit interview questionnaires

6. Question one asked what attracted them to work at the HTA. The responses to this question were varied. For some it was the opportunity to work in health / government / regulation, for others it was the opportunities that the specific role gave them.
7. Question two asked whether their induction into the HTA met their needs. 60% said that their induction had met their needs, and for 40% it had not. In all of the cases where people had said their induction did not meet their needs, those people joined the HTA before the Learning and Development Framework was put into place in March 2009 and did not get an Induction Workbook to use for the first 6 months in their role. All those that said their induction met their needs

joined after March 2009 and most commented that the induction was well structured and the workbook was very useful.

8. Question three required a rating out of 5 (1 being poor, 5 being excellent), against various aspects of their employment. The aspects that rated below average were promotion prospects (1.3) and training and development prospects (2.8). The rating that was highest was relationship with colleagues (4.2) and all other aspects such as relationship with line manager (3.5), salary and benefits (3.2), job satisfaction (3.2), working environment (3.9), communication within directorates (3.3) rated higher than the middle score of 3.
9. Question four asked about expectations with regard to their role in the HTA. 76% said that their expectations were met and 24% said that their expectations were not met. Some of the reasons that people's expectations were not met were due to not being given as much responsibility as expected, others said that workload was too high and there was no recognition of this, and one said that procedures weren't taught properly.
10. Question five asked if they had received an appraisal of their performance in the preceding 12 months. The exit interview results indicated that 25 out of 27 people had their performance appraised within the 12 months before leaving. The two that had not, one was a short fixed term contract, and the other was a contractor.
11. Question five also asked if they were happy with the way that their performance was measured and the feedback that was given. Out of 26 responses, 54% of people said that they were happy with their performance appraisal and feedback. 46% said that they were either not happy with the appraisal process, or the feedback given by their manager or the rating that they received. This is a significant result which indicates more work needs to be done on the performance management process and ensuring that line managers are equipped with the ability to measure performance accurately and give feedback appropriately.
12. Question six asked if there was a satisfactory balance between work commitment and commitments outside of work. Out of 26 responses, 85% of people said that they had a satisfactory balance between work commitments and commitments outside of work. The comments made by the 15% who felt they didn't have a satisfactory work/life balance were varied. One response was that it was a personal preference to be moving to a part time job, and nothing that the HTA could have changed. One response was from an RM who felt that RM's work longer hours on average due to travelling on inspection and that more recognition should be given to this. The remaining two people felt that

their role was too big, because of this they worked longer hours and this impacted on their work/life balance.

13. Question seven asked for commentary on the best two aspects of working at the HTA. An overwhelming number of people said it was their intelligent, helpful, talented, experienced colleagues that made it great to work at the HTA. The second best aspect was a mixture of various reasons such as challenging and interesting work, the variety and diversity of work and projects to work on and working with stakeholders.
14. Question eight asked for the worst two aspects of working at the HTA. This question produced a huge variety of responses. By categorising the comments the highest number were regarding promotion limitations for various reasons, lack of leadership, and lack of communication. However lack of communication has not been mentioned as one of the worst aspects since October 2010. This might suggest that communication within the organisation is getting better. Lack of leadership has still been raised frequently in the last 12 months.
15. Question nine required a rating of the experience at the HTA overall from 1 (poor) to 5 (excellent) and the reasons for their rating. The average rating of everyone that responded to this question is 3.6. This is above the middle of the scale. Generally people made a comment that there were some good aspects and some bad aspects of the job and organisation, but most people overall felt that they had got something out of working at the HTA. It seems that this is quite a good average rating considering that it is given at the time when people are just about to leave the organisation.
16. At Question 10, 63% of people said that they would come back to work for the HTA if the opportunity or the right role arose, or the things that they hadn't like had changed. Some of the 37% of people that said they wouldn't come back, it was because they never go back to previous organisations and for others it was because they were taking a different career path so didn't think that would lead them back to the HTA.
17. Question 11 asked about reasons for leaving. There was a variety of responses to this question however the one that was most prevalent was moving to a more challenging role and looking for career progression (56%). Other responses were personal reasons like working closer to home, working part time, studying full time or moving overseas.
18. Question 12 asked if there was anything that could have kept them at the HTA. 27% of people said that nothing would have encouraged them to stay. 73% said they would have stayed for a variety of reasons, the most common one being a promotion, more money, change of role or more development within their role.

Conclusion

19. Overall the exit interview data has given some insights or corroborates with the types of information that SMT is receiving from the Staff Forum, staff meetings and anecdotally.
20. One of the most significant results in this exercise that has been identified is that people are not clear on the objectives of the performance management process and appraisal system. A review of the performance management system is underway for introduction by the end of the current reporting year.
21. Other actions are also in train to address further issues raised by the analysis e.g. review of learning and development opportunities.

STRATEGIC PERFORMANCE REVIEW FRAMEWORK 2011-12

Unique ref	Strategic Aim Ref	Directorate Owner	Corporate Business Objectives	Indicator type	Performance indicators	Delivery Update													
						A	M	J	J	A	S	O	N	D	J	F	M	Comments	
1. To continuously improve the efficiency and effectiveness of our regulatory activity, and our advice and guidance a) To fulfil the HTA's statutory remit b) To share knowledge and experience gained from regulation and to help licensed establishments better meet HTA standards of quality c) To work internally and with other regulators and the organisations we licence to streamline and improve regulatory processes and practices																			
KPI 1.1	a	Regs	To license five sectors under the Human Tissue Act	Measure	At least 90% of completed new licence applications are processed within 20 working days of completion of the site visit inspection														QTR 1 - JB - 2 complete applications received and a licensing decision made. 2 applications were identified as incomplete. Pilot LAAV being considered for Q3.made.
KPI 1.2	a	Regs		Measure	At least 90% of variations to licences are processed within 20 working days of receipt														APR - JB - x19 variations received and completed within timeframe MAY - JB - 19/21 variations completed within timeframe JUN - JB - 18/19 variations completed within timeframe JUL - JB - 58/59 of variations completed within timeframe AUG - 98% of variations completed within timeframe
KPI 1.3	a	Regs		Measure	At least 90% of new licence applications to include a site visit inspection														QTR 1 - JB - Pilot LAAV being considered for Q3.
KPI 1.4	a	Regs	To inspect Human Application establishments regulated under the Q&S Regs	Measure	At least 81 site visit inspections to take place during the business year (Reported quarterly against profiled inspections).														QTR 1 - JB - 28/30 HA inspections conducted. 1 establishment couldn't accommodate us due to staff being away & other commitments. 1 establishment requested to be inspected closer to 2 yearly point - it has been reprogrammed for Sept 11.
KPI 1.5	a	Regs		Measure	At least 90% of inspection reports published within 12 weeks of the end of the inspection														APR - JB - 7/7 inspection reports published MAY - JB - 2/3 inspection reports published. 1 report was delayed during the QA process. JUN - JB - 9/11 published in time. 1 report was late as changes were unable to be made to a PDF report (process clarified to avoid in future). 1 report was late at draft & final stages which had a knock on affect. Report tracking at weekly Regulation Governance meetings should prevent any further significant delays to reports in the publication process. JUL - JB - 13/14 published in time. AUG - 100% published in time.
KPI 1.6	a	Regs		Measure	At least 90% of responding establishments rate the overall inspection process as either 'good' or 'excellent' (reported quarterly)														
KPI 1.7	a	Regs		Measure	At least 90% of Corrective and Preventative Actions (CAPAs) are completed within agreed timescales														APR - JB - 8/16 CAPAs are open beyond their April deadline MAY - JB - 27/50 CAPAs completed within timeframe. 19 CAPAs are incomplete due to the DI being on leave, 3 CAPAs are incomplete due to the DI resigning without notice & 1 CAPA is incomplete pending further evidence from the DI. JUN - JB - 18/27 completed in timeframe. 6 CAPAs are incomplete as the DI has requested further time, the lead RM has agreed to this and is monitoring. 3 CAPAs are being chased by the lead RM. RMs reinforcing with DIs the importance of setting realistic timescales and meeting them. JUL - JB - 6/19 MAJOR CAPAs completed in timeframe. Remaining CAPAs relate to 3 different inspections. 11 CAPAs have had evidence submitted within the timeframe - the RM is currently assessing. 1 CAPA is being chased and the remaining CAPA is awaiting an update from the RM. AUG - JB - 3/7 MAJOR CAPAs completed in timeframe. Outstanding CAPAs relate to 2 inspections (11083 & 22520). 11083 has been asked to submit more info. 22520 will provide an update during Sept or during their non-routine inspection on 28-29/09/11.
KPI 1.8	a	Regs	To provide advice and guidance to licensed establishments	Measure	At least 95% of enquiries are answered within 10 working days of receipt														APR - JUN - JB - Reported against 10/11 KPI (20 working days) until CRM is updated to allow us to report against 10 working days. JUL - JB - Reporting against 11/12 business plan target of 10 working days (following CRM update) AUG - 97% within 10 working days
KPI 1.9	a	Regs	To undertake activity to implement the requirements of the Organ Donation Directive	Milestone	Project Red-Amber-Green (RAG) status remains Green or Amber during project implementation stage.														JUN - IS - Currently all work packages associated with the ODD are on target. DH have changed the deadline for consulting on the Regs - this may result in us deciding to do the same re our Directions - however. This shouldn't affect the timelines for the project as a whole. AUG - IS - Project plan has been reviewed to assess impact of late consultation and slow progress of SI through various committees. Currently, project is still on target to meet full implementation by 27 August 2012
KPI 1.10	b	Regs	To inspect PM, Anatomy, Research and Public Display establishments regulated under the HT Act	Measure	At least 104 site visit inspections to take place during the business year (Reported quarterly against profiled inspections).														QTR 1 - JB - 27/27 scheduled inspections conducted.
KPI 1.11	b	Regs		Measure	At least 90% of inspection reports published within 12 weeks of the end of the inspection														APR - JB - 9/9 inspection reports published within time frame. MAY - JB - 2/2 inspection reports published within time frame. AUG - 100% within time frame.
KPI 1.12	b	Regs		Measure	At least 90% of responding establishments rate the overall inspection process as either 'good' or 'excellent' (reported quarterly)														JUL - 97%
KPI 1.13	b	Regs		Measure	At least 90% of Corrective and Preventative Actions (CAPAs) are completed within agreed timescales														
KPI 1.14	c	Strat	To manage the work stream associated with assessing non genetically or emotionally related directed donations	Milestone	Assessment process in place for these cases by end of Q3														(Jun) PMG meeting held on 28 June 2011 to move this issue forward (Jul) July Authority Meeting agreed a paper setting out the next steps for completion of the project by the end of the business year. (Aug) September Authority meeting will receive a further update on progress with this project.
KPI 1.15	c	Strat		Milestone	Guidance for transplant teams revised, published and has the support of the transplant community by end Q4														(Jul) July Authority Meeting agreed a paper setting out the next steps for completion of the project by the end of the business year. (Aug) September Authority meeting will receive a further update on progress with this project.

