

## Minutes of the fiftieth meeting of the Human Tissue Authority

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**Date** 26 July 2011

**Venue** Wellcome Collection  
183 Euston Road  
London  
NW1 2BE

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### 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
<b>Item 1</b>	<b>Welcome and apologies</b>	
	<ol style="list-style-type: none"> <li>1. Baroness Warwick welcomed Members and observers to the fiftieth meeting of the Human Tissue Authority.</li> <li>2. Apologies had been received from Mrs Rosie Glazebrook, Professor Gurch Randhawa and Dr Andrew Reid.</li> </ol>	
<b>Item 2</b>	<b>Declarations of interest</b>	
	<ol style="list-style-type: none"> <li>3. There were no declarations of interest.</li> </ol>	
<b>Item 3</b>	<b>Minutes of 24 May 2011 [paper: HTA (33/11)]</b>	
	<ol style="list-style-type: none"> <li>4. The minutes of 24 May 2011 were adopted.</li> </ol>	
<b>Item 4</b>	<b>Matters arising</b>	
	<ol style="list-style-type: none"> <li>5. All actions from the previous meeting had been completed or were in hand.</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>9. The HTA's contribution to the Big Society will be discussed at the September Authority meeting.</li> </ol>	
<b>Item 5</b>	<b>Chair's report</b>	
	<ol style="list-style-type: none"> <li>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.</li> <li>11. The Director of Regulation post is now vacant and has</li> </ol>	

	<p>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>	
<b>Item 6</b>	<b>ALB review and shared services update [paper: HTA (34/11)]</b>	
	<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 noted that recent media coverage of the Care Quality Commission (CQC) displayed the breadth of the</p>	

	<p>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>	
<b>Item 7</b>	<b>Update on the implementation of the Organ Donation Directive [paper: HTA (35/11)]</b>	
	<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> <p>30. The Authority noted the contents of the paper.</p>	

<b>Item 8</b>	<b>Regulatory Activity Report 1 April to 30 June 2011 [paper: HTA (36/11)]</b>	
	<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><b>Action: Classification of SUIs to be discussed at the Histopathology Working Group meeting on 13 September.</b></p>	<b>AC</b>
<b>Item 9</b>	<b>Framework for living organ donation assessment - update [paper: HTA (37/11)]</b>	
	38. Allan Marriott Smith provided background information on this issue and detailed the previous discussions of the Authority on this matter.	

	<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"> <li>i. Over 50% of all kidney donations were from living donors.</li> <li>ii. This figure was over 70% at the Rotterdam centre.</li> <li>iii. There are more unrelated living donors than related living donors.</li> <li>iv. Most unrelated donors donate to their partner.</li> <li>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.</li> <li>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.</li> <li>vii. The same approach is taken for all donors, there is no differentiation on the basis of relationship.</li> <li>viii. A psychosocial assessment of the donor is conducted by the coordinator and a Social Worker.</li> <li>ix. The decision on whether to proceed with the donation is made by the clinical team.</li> <li>x. An additional psychiatric assessment of altruistic donors is required.</li> <li>xi. Between 2000-2010, ten people have chosen to direct their donation to a person with whom they have no genetic or emotional relationship.</li> </ol> <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 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</p>	
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	<p>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><b>Action: To further investigate the psychosocial assessment carried out in the Netherlands.</b></p> <p><b>Action: To update the police referrals SOP as necessary.</b></p>	<p>AMS</p> <p>AMS</p>
<p><b>Item 10</b></p>	<p><b>Report on the living organ donation system – January to June 2011 paper: HTA (37/11)]</b></p>	
	<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>	
<b>Item 11</b>	<b>Financial Report June 2011 [paper: HTA (39/11)]</b>	
	<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>	
<b>Item 12</b>	<b>Report from Audit Committee 2 June 2011 [paper: HTA (41/11)]</b>	
	<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 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>	

	62. The Authority noted the contents of the paper.	
<b>Item 13</b>	<b>Strategic Performance Review June 2011 [paper: HTA (42/11)]</b>	
	<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>	
<b>Item 14</b>	<b>Report on enquiries 1 April to 30 June 2011 [paper: HTA (42/11)]</b>	
	<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 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><b>Action: Complaints against licensed establishments to be</b></p>	<b>SG</b>

	<b>reported as referrals in future.</b>	
<b>Item 15</b>	<b>Update on the Communications Strategy (Oral)</b>	
	<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>	
<b>Item 16</b>	<b>Any other business</b>	
	<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>	
<b>Item 17</b>	<b>Question and Answer session</b>	
	83. A question and answer session followed the main meeting.	

The meeting closed at 1.00 pm