

Minutes of the fifty-first meeting of the Human Tissue Authority

Date 27 September 2011

Venue The Westminster Conference Centre
1 Victoria Street
London
SW1H 0ET

Present

Members

Baroness Diana Warwick (Chair)
Mrs Jodi Berg
Mr Brian Coulter
Professor Susan Dilly
Mrs Rosie Glazebrook
Mrs Pamela Goldberg
Professor Gurch Randhawa
Dr Andrew Reid
Mr Keith Rigg
Ms Catharine Seddon

In attendance

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

Ms Vickie Evans (HR Manager)
Mrs Stacey Pengelly (Quality and Policy Manager)
Ms Sarah-Jane Wakefield (Head of Communications)

Observers

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

Item	Title	Action
Item 1	Welcome and apologies	
	<ol style="list-style-type: none"> 1. Baroness Warwick welcomed Members and observers to the fifty-first meeting of the Human Tissue Authority. Peter Jones, who will be retiring from the Department of Health at the end of October, was thanked for his input and support over the previous six years and the Authority wished him well. 2. Apologies had been received from Professor Michael Banner and Mrs Suzanne McCarthy. 	
Item 2	Declarations of interest	
	<ol style="list-style-type: none"> 3. There were no declarations of interest. 	
Item 3	Minutes of 26 July 2011 [paper: HTA (43/11)]	
	<ol style="list-style-type: none"> 4. The minutes of 26 July 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. The Histopathology Working Group (HPWG) met on 13 September and the meeting was positive and cooperative. The issue of the HTA's requirements for the traceability of blocks and slides was raised and it was agreed that this would be considered by a sub-group of the HPWG. There was a call for the HTA to consider whether Serious Untoward Incidents (SUIs) should be renamed to prevent any confusion as the same term being used in hospitals for different occurrences. "Adverse Incidents" was suggested as an alternative. 7. The Standard Operating Procedure (SOP) on Police Referrals had been reviewed and it was confirmed that this does cover the potential referral of living donation cases where there is suspicion of reward. 8. The term "referrals" will now be used for complaints raised with the HTA against both licensed establishments and other bodies. 9. The Senior Management Team (SMT) discussed the HTA's contribution to the Big Society and agreed that as there has not yet been a specific request to submit evidence of this, no further work will be done on this at present. 	

Item 5	Chair's report	
	<p>10. The Chair gave an update on the appointment of a new Director of Regulation. As the role had not been filled through the internal channels, an advert had been placed in The Times and The Guardian. Sixteen applications had been received and interviews were scheduled for 5 October. Alan Clamp and the three Heads of Regulation were covering aspects of the role until the new person started.</p> <p>11. There had been three meetings of the Welsh Government's Expert Reference Panel on the introduction of presumed consent. This issue is covered in more detail at Item 9.</p> <p>12. Members of the executive and Authority attended the European Society for Organ Transplantation (ESOT) Conference earlier in the month. This was the first conference of this scale in the UK and a wide range of clinical, legal and ethical matters were discussed.</p> <p>13. The Chair and acting Chief Executive met with Valerie Vaz, a member of the Public Bodies Bill Committee, on 19 September. The meeting was constructive and Ms Vaz requested further briefing from the HTA. It was suggested that we make contact with the Health Select Committee and offer to brief as appropriate. There had been some contact with Stephen Dorrell MP in the past.</p> <p>14. The British Medical Association (BMA) wrote to the Department of Health (DH) at the end of August stating their preference for the HTA's functions to be separated. A copy of this letter, the DH's response, and the HTA's letter responding to the BMA had been circulated to Members.</p> <p>15. An article in the Sunday Times in September covered the case of a British woman who had sought a kidney donor through The Flood Sisters Foundation of America. The HTA worked closely with those involved to ensure a consistent message was given to the media. This story led to further coverage on the following Monday.</p> <p>16. The Daily Mail had run an article on the items bought using the Health Protection Agency's (HPA) government procurement card (GPC). The HTA received a Freedom of Information request (FOI) for the same information earlier in the year.</p> <p>17. A journalist working for Private Eye had contacted us regarding the potential destruction of research samples. It was not yet clear when this story would run.</p>	

	Action: To make contact with the Health Select Committee (post meeting note – Valerie Vaz is a member of this Committee)	SGr
Item 6	ALB review and shared services update [paper: HTA (44/11)]	
	<p>18. Alan Clamp introduced the paper and confirmed that the DH intends to issue the consultation on its plans for the transfer of the HTA's functions by the end of the year.</p> <p>19. There has been a commitment by the DH that the HTA will have sight of the consultation document prior to publication to ensure the content is accurate. A reasonable amount of time will be allowed to review the document.</p> <p>20. Stakeholders have been divided into three tiers and the level of engagement with each will reflect the tier they sit within. The HTA will have the opportunity to feed in to the stakeholder lists.</p> <p>21. An impact assessment will be developed for the consultation and this will cover the economic and regulatory arguments for transferring the HTA's functions to another body. When a decision has been made about what will definitely happen to the functions, a further impact assessment will be developed to reflect the firm proposal.</p> <p>22. There has been agreement that those organisations involved in the DH's shared services agenda will have more involvement in the governance of the project and it has been recommended that there is a one-off meeting of all involved to ensure a common view on how this will work.</p> <p>23. The importance of consulting with patient groups was stressed, as well as ensuring that the exercise is promoted widely using a variety of means (e.g. e-newsletter).</p> <p>24. The Authority noted the content of the paper.</p> <p>Action: To pass on stakeholder details to DH, where appropriate and with prior approval.</p>	SGr
Item 7	Update on the implementation of the Organ Donation Directive [paper: HTA (45/11)]	
	<p>25. Alan Clamp introduced the paper and gave an oral update 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. There has been a delay in the draft statutory instrument (SI) passing through the Regulatory Policy Committee (RPC) as there were follow up questions on the impact assessment (IA) which supported the SI. This has now</p>	

	<p>been resubmitted and a response from the RPC is due in the next week.</p> <p>27. The next step will be for the SI and IA to be considered by the Reducing Regulation Committee (RRC) and once it is satisfied, the consultation can start. The SI and IA will be considered by the RPC and RRC once again, after consultation.</p> <p>28. It is now thought that the consultation period will begin in late October, and the DH is seeking to reduce this to an eight week period, from the recommended 12.</p> <p>29. The risk that the Regulations are not in place before the 27 August has increased and as such the project team are looking at a range of contingency plans. We will be able to accept and process applications before the Regulations are in force but would not be able to take any regulatory action until the Regulations have been made.</p> <p>30. Imogen Swann, Head of Regulation, was attending the first meeting of Competent Authorities in Brussels and an update on this would be given at the November meeting.</p> <p>31. Discussion had taken place as to whether the HTA's statutory responsibility to assess all cases of living organ donation presented a conflict of interest with being the Competent Authority. The DH does not consider this a problem.</p> <p>32. There are three possible options on how the EUODD progresses in the UK. The Government could make the decision not to implement at all; the project may continue as planned; or the decision could be made to implement the directive in a different manner. The last of these options would be the most difficult to respond to.</p> <p>33. The Authority noted the content of the paper.</p> <p>Action: To provide an update on the Competent Authorities meeting at the November meeting.</p>	AC
Item 8	Revision of the HTA's Codes of Practice [paper: HTA (46/11)]	
	<p>34. Allan Marriott Smith introduced the paper which laid out the plans to redraft the Code of Practice on the Donation of Solid Organs for Transplantation to reflect the EUODD.</p> <p>35. The HTA Management Group (HTAMG) had asked for a further paper to be drafted considering the potential benefits and disbenefits of reviewing and updating all the Codes of Practice. The outcome of the discussion at HTAMG will be reported at the November meeting.</p> <p>36. Consideration will be given to the development of a Code of</p>	

	<p>Practice on the definition of death and this will be an agenda item for a future meeting of the Policy and Regulatory Activity Group (PRAG).</p> <p>37. Members suggested that the level of risk posed by any inaccuracy in a Code of Practice should be taken into consideration when deciding how and when to issue updates.</p> <p>38. Both the British Transplantation Society (BTS) and the UK Donation Ethics Committee (UKDEC) are considering issues around donation after circulatory death, and combined with the Association of Medical Royal Colleges (AoMRC) document on the diagnosis of death, it was considered that there was already a significant amount of information available on the diagnosis of death.</p> <p>39. The Authority noted the content of the paper.</p> <p>Action: To provide an update on the decision on the revision of the other Codes of Practice at the November meeting.</p>	AMS
Item 9	Report on the introduction of presumed consent in Wales [paper: HTA (47/11)]	
	<p>40. Allan Marriott Smith provided background information on the Welsh Government's proposal to introduce presumed consent for organ donation.</p> <p>41. A letter was sent to the Chair of the Expert Reference Panel established by the Welsh Government to confirm that the HTA was represented in an advisory capacity, and our membership of the group did not imply support for the proposal.</p> <p>42. A white paper is due to be published in early November and a further paper will be drafted covering the HTA's options for responding to this.</p> <p>43. There was discussion of the HTA's responses to the two consultations which took place earlier in the year, and concern was expressed that the HTA's tone could be construed as being opposed to presumed consent. However, it was broadly thought that the responses accurately reflected the position of the Authority.</p> <p>44. It will be important to understand whether the Welsh Government intends to introduce a system of presumed consent or an opt-out system, as they have different implications.</p> <p>45. There was concern about a range of cross border issues and it was confirmed that the Welsh Office would liaise with the DH on practical issues once the white paper had been</p>	

	<p>published.</p> <p>46. Members suggested that we seek legal advice on both the potential impacts to the HTA as regulator, and to citizens.</p> <p>47. The Authority noted the content of the report.</p> <p>Action: To bring a firm proposal on responding to the Welsh Government consultation to the November meeting</p>	AMS
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Item 10	Framework for living organ donation assessment – update [paper: HTA (48/11)]	
	<p>48. Allan Marriott Smith introduced the paper which builds on the discussions at the July Authority meeting and Review of the Year event. SMT, external contacts and the Chair have all been involved in the development of the proposals.</p> <p>49. Those cases which fall within the categories marked as higher risk will be assessed by a panel of three Authority members. More work needs to be done on the development of these categories and this will be done at the Independent Assessment Working Group (IAWG) meeting on 25 October.</p> <p>50. A pilot will be run initially in order that no significant changes are made to existing systems without understanding whether they will deliver the outcomes we expect.</p> <p>51. We must ensure that we remain within our remit and assess on the basis of evidence of reward, duress and coercion. Any measures introduced should be objective, and enable the HTA to be satisfied that the case meets the standards for approval.</p> <p>52. It was recommended that the suggested signed statement allows section 9 of the Criminal Justice Act to be applied.</p> <p>53. There was a discussion about who should carry out the psychosocial assessment, and while there would be benefits of a Social Worker doing this, it was more likely that a Psychiatrist or Psychologist would be accessible by the transplant unit.</p> <p>54. The Authority noted the content of the report.</p>	
Item 11	Communication Strategy - update [paper: HTA (49/11)]	
	<p>55. Shaun Griffin introduced the report and explained that it had been discussed at the Communications Members' Group and would be brought to the full Authority meeting twice a year.</p> <p>56. Members would find more hard data on enquiries useful to</p>	

	<p>get a fuller picture of the range of enquires received and how much time is spent on them. A project was underway on how the HTA handles enquiries and the outcomes and outputs of this will be fed back to the Authority.</p> <p>57. Clarity was provided on the public outreach project and it was confirmed that we would be exploring the reasons some people had confidence in the regulation of human tissue, and others did not. It was explained that this project was designed to support the Communications Strategy with anecdotal information on the views of the public.</p> <p>58. It was noted that there was an upsurge in the number of downloads of documents from the website following the issuing of a communication.</p> <p>59. The Authority noted the content of the paper.</p> <p>Action: To label the annexes clearly on future versions of the Communications Strategy update report</p>	SGr
Item 12	Financial report August 2011 [paper: HTA (50/11)]	
	<p>60. Sue Gallone presented the report which gave the financial position as at the end of August.</p> <p>61. We have had £108k more income and £228k less expenditure than forecasted so far this year, and credits will be issued to establishments as they were last year. The total figure to be credited is likely to be c. £500k.</p> <p>62. The lower expenditure is primarily linked to the number of vacant posts.</p> <p>63. The debtors' position is better than it has been in previous years and reminders have proved largely successful. When reminders have not worked the debt has been referred to legal, and due to limited resources it has not been possible to action these as quickly as hoped, however legal letters would be issued this week.</p> <p>64. There was concern that the Regulation Directorate was under spent on salaries by 15% and the impact this had on the number of inspections carried out. It was confirmed that assessment of this had taken place and consideration given to how many inspections it will be possible to undertake in the remaining two quarters of the year. One new Regulation Manager started in July and two more will be joining later in the year.</p> <p>65. It was noted that the Human Fertilisation and Embryology Authority (HFEA) has home based inspectors and there may be benefit to considering more flexible working to fill these roles.</p>	

	<p>66. There had not been any feedback from stakeholders that the issuing of credit notes was damaging the HTA's reputation and some had commented that the credit would allow them to do other work.</p> <p>67. The decision had been made to disassociate non-payment of fees with regulatory action as this had not proved successful. Persistent non-payers will be perused through the county court as this is more proportionate.</p> <p>68. The reserves are currently artificially high and will fall to £1m.</p> <p>69. The Authority noted the content of the paper.</p>	
Item 13	Strategic Performance Review August 2011 [paper: HTA (51/11)]	
	<p>70. Allan Marriott Smith introduced the paper and provided further information on the leavers' analysis which had been carried out.</p> <p>71. The most significant issue to come out of the analysis was that of Personal Development Plans (PDPs) as the existing system isn't felt to add value. Proposals on how this system can be improved were presented at the last staff meeting.</p> <p>72. Training and development had also been identified as an area for improvement, and consideration is being given on offering staff support in developing their careers with more long term courses.</p> <p>73. Three leadership and management seminars will take place over the coming weeks as a less formal method of training.</p> <p>74. For most leavers, money was not cited as a reason why they considered another job outside the HTA; the lack of opportunities for promotion, the absence or quality of training and development, and the lack of opportunities to work on interesting projects were the key reasons given for leaving.</p> <p>75. Most people leaving did not cite uncertainty about the future of the HTA as a reason. However, consideration should be given to succession planning, especially for high profile roles.</p> <p>76. The Authority noted the content of the paper.</p>	
Item 14	Any other business	
	<p>77. There was a brief discussion on "body farms" and how they would fit into the HTA's regulatory framework. Initial discussions had been held with those seeking to establish the first body farm in the UK and it is likely to be the Home</p>	

	<p>Office or Ministry of Justice which will lead on this.</p> <p>78. A statement and lines to take have been prepared on body farms to respond to enquiries after the television drama on this aired. The term for the study of decomposing bodies is taphonomy.</p> <p>79. The public meeting and Review of the Year event next year will be held on Tuesday 10 July so not as to coincide with school holidays.</p> <p>Action: To bring a paper on body farms to the January meeting</p> <p>Action: To circulate the dates of forthcoming meetings.</p>	<p>AC</p> <p>AMS</p>
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The meeting closed at 1.00 pm