

Fiftieth Meeting of the Human Tissue Authority

Date 26 July 2011
Time 10.30am – 1.00 pm
Venue Wellcome Collection Conference Centre
183 Euston Road
London
NW1 2BE

Agenda

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

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 24 May 2011 HTA (33/11)
4. Matters arising
5. Chair's report Oral
6. ALB review and shared services update (I) HTA (34/11) CEO
7. Update on the implementation of the Organ Donation Directive (I) HTA (35/11) AC
8. Regulatory Activity Report 1 April to 30 June 2011(I) HTA (36/11) AC
9. Framework for living organ donation assessment (D). Item includes a presentation from Emma Massey HTA (37/11) AMS
10. Report on the living organ donation system (I) HTA (38/11) AMS
11. Financial report June 2011 (I) HTA (39/11) SM
12. Report from the Audit Committee 2 June 2011 (I) HTA (40/11) SM
13. Strategic performance review June 2011 (I) HTA (41/11) AMS
14. Report on enquiries 1 April to 30 June 2011 (I) HTA (42/11) SG
15. Update on the Communications Strategy (I) Oral
16. Any other business

The meeting will be followed by a Q and A session.



Minutes of the forty-ninth meeting of the Human Tissue Authority

Date 24 May 2011
Venue The Westminster Conference Centre
 1 Victoria Street
 London
 SW1H 0ET

| Present | |
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| <p>Members Baroness Diana Warwick (Chair) Professor Michael Banner Mrs Jodi Berg Mr Brian Coulter Professor Susan Dilly Mrs Rosie Glazebrook Mrs Pamela Goldberg Mrs Suzanne McCarthy Professor Gurch Randhawa Mr Andrew Reid Ms Catharine Seddon</p> | <p>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)</p> <p>Ms Caroline Browne (Head of Regulation) (Items 8 and 9)</p> <p>Observers Mr Peter Jones (Department of Health) Mr Patrick Irwin (Department of Health)</p> |

| Item | Title | Action |
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| Item 1 | Welcome and apologies | |
| | <ol style="list-style-type: none"> 1. Baroness Warwick welcomed Members and observers to the forty-ninth meeting of the Human Tissue Authority. 2. Apologies had been received from Mr Keith Rigg. 3. The Chair welcomed Victoria Marshment as the newly appointed Head of Performance and Authority Secretary. | |
| Item 2 | Declarations of interest | |
| | <ol style="list-style-type: none"> 4. There were no declarations of interest. | |
| Item 3 | Minutes of 22 March 2011 [paper: HTA (21/11)] | |
| | <ol style="list-style-type: none"> 5. The minutes of 22 March 2011 were adopted. | |
| Item 4 | Matters arising | |
| | <ol style="list-style-type: none"> 6. All actions from the previous meeting had been completed or were in hand. 7. Allan Marriott Smith provided an oral update on progress with the work on organs that cannot be transplanted to the intended recipient. Guidance (including a recommended consent form and information sheet) was sent to transplant units on 16 May. The process will become operational on 31 May, and a review will be undertaken after six months to assess the efficacy of the process. Input will be sought from NHSBT and transplant units. | |
| Item 5 | Chair's report | |
| | <ol style="list-style-type: none"> 8. The Chair gave an update on the recruitment of the new Chief Executive. The role had been advertised on the Department of Health, NHS and Civil Service internal recruitment websites with a closing date for applications of 30 May. Craig Muir had secured the agreement of the Department of Health to remain on secondment to the HTA until the end of September. 9. The Chair gave an overview of this year's Member appraisal process. There was general agreement that the Board was working well. Members were clear in their role as a critical friend to the Executive and felt there was a good balance in membership. Members had expressed a desire to gain a better understanding of the different sectors the HTA regulates and of the other regulators in the health sector. The Chair will work with the Executive to develop a learning and development programme. | |

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| | <p>10. The Chair informed Members of changes to the membership of the Audit Committee. Michael Banner will continue to chair the Committee to ensure a smooth transition to the new internal audit arrangements. Brian Coulter will step down following the June meeting. The Chair thanked Brian for his contribution to the work of the Committee. Catharine Seddon will join the Committee from September and a further Member will be appointed when Professor Banner stands down as chair in June 2012.</p> <p>11. The Chair updated Members on progress with an employment tribunal case involving an ex-HTA staff member.</p> <p>12. The Chair attended the All Party Parliamentary Group (APPG) on Transplantation on 10 May. Keith Rigg was a member of the panel. Subsequently, Paul Uppal MP, a member of the APPG, laid a Parliamentary Question on the future of the HTA's living organ donation function. The response confirmed the Government's preference to transfer this function to the Care Quality Commission (CQC).</p> <p>13. The Chair attended the EUODD workshop event on 19 May, jointly hosted by the HTA and NHSBT, which had proved a very successful day (see Item 7).</p> <p>14. The Communications Strategy had started well with a half page article on altruistic organ donation in The Observer. The Chair thanked Sara Coakley and the transplant team for the work they had done on this and noted that this was a one of a number of media opportunities that had been created. Members were interested as to whether media coverage increased the number of website hits.</p> <p>Action: To identify further learning and development opportunities for Members including a programme of seminars.</p> <p>Action: To produce a quarterly report on the delivery of the Communications Strategy, including relevant information on website hits.</p> | <p>AMS</p> <p>SG</p> |
| <p>Item 6</p> | <p>ALB review and shared services update [paper: HTA (22/11)]</p> | |
| | <p>15. Craig Muir introduced the paper which provided an update on progress with implementing the recommendations of the ALB review. It is still the Government's intention that the HTA's functions remain together, although there is still a question about the location of our research functions.</p> <p>16. The Public Bodies Bill is now with the House of Commons, the second reading stage is planned to begin in late May/early June.</p> | |

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| | <p>17. The HTA is working closely with the CQC and is seeking to take discussions forward on a tripartite basis including the HFEA. Current work focuses on two main areas: frontline regulation and governance.</p> <p>18. The Chair and Chief Executive had undertaken a joint session to update staff on the latest progress with the Bill. Although the uncertainty about the HTA's future has placed pressure on the HTA team, morale is generally thought to be good, with the success of the ODD workshop providing a boost to the organisation.</p> <p>19. Sue Martin provided an update on progress with the shared services agenda.</p> <p>20. Members expressed concern that governance of shared services can be problematic, especially in the areas of payroll and transactional finance. It will be particularly important for the HTA to retain control over its strategic finance and communications functions and if these were in any way jeopardised by the shared services agenda, the Authority should consider escalating this within the Department of Health.</p> | |
| Item 7 | Update on the implementation of the Organ Donation Directive [paper: HTA (23/11)] | |
| | <p>21. Alan Clamp gave an oral update the EUODD Workshop. A hundred delegates attended and two thirds of transplant centres were represented. Although there was a potentially difficult message to communicate, the day went exceedingly well.</p> <p>22. Delegates identified a manageable number of issues and acknowledged that it was better to be aware of these at this stage rather than later in the process. Feedback had been broadly positive, with 90% of attendees agreeing the event was useful.</p> <p>23. The Department of Health will be consulting on the draft Statutory Instrument for three months from August 2011. Directions will be issued by the end of the calendar year. Licence fees will be announced in December 2011 and there will be a programme of workshops for Designated Individuals delivered in early 2012.</p> <p>24. 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>25. The commitment of the HTA's partners; NHSBT, the Department of Health and transplant centres was very high at the workshop and there is no reason to suggest at this</p> | |

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| | <p>stage this will drop.</p> <p>26. The Executive reported that it is working on contingency plans if further resource is required in order to deliver the organ donation directive by August 2012. A paper will be presented to the June Members group on the approach being taken.</p> <p>27. Ring-fenced funding from the Department for the implementation of the EUODD is being used to pay the costs of staff who have been redeployed onto this project. This provides scope within the budget to recruit if necessary.</p> <p>28. The Authority thanked the team working on the EUODD for their hard work and commitment.</p> <p>Action: Business plan prioritisation to be an agenda item at the Members' Group meeting on 28 June.</p> | AMS |
| Item 8 | Update on post mortem tissue retention in Home Office cases [paper: HTA (24/11)] | |
| | <p>29. Alan Clamp introduced the paper. There is a need to support coroners and pathologists to ensure tissue is not retained without consent. Confusion exists as there are different legislative provisions which apply in certain circumstances and it is not always clear which should be followed. There is broad consensus it will be beneficial if communication channels between coroners and pathologists are open, well established and standardised.</p> <p>30. The report on the results of the police audit of retained tissue from all 50 police forces will be published in 2013. A new Code of Practice for forensic pathologists is in the final stages of development and guidance on the legal issues in forensic post mortems is due to be published.</p> <p>31. Members suggested that the HTA provide information to support families who are going through this process, which will allow them to ask questions. It is important the police understand they have a pivotal role in ensuring they communicate when the retention of tissue is no longer required under PACE. It is also important that the interface with pathologists is established at the mortuary where the tissue is being held.</p> <p>Action: To consider developing public facing documents on processes relating to Home Office and other post mortem examinations.</p> <p>Action: To facilitate communication between Home Office Pathologists and establishments where tissue may be stored.</p> | AC/SG AC |

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| Item 9 | Post Mortem Sector Report – June 2011 [paper: HTA (25/11)] | |
| | <p>32. Alan Clamp introduced the paper which had been redrafted following the March meeting. The main body of the report will be published on the HTA website, and the accompanying annexes will be sent directly to the establishments and Designated Individuals. Susan Dilly and Suzanne McCarthy were thanked for providing input and editing support .</p> <p>33. Generally speaking establishments had been co-operative and accepted that they were required to complete the audit. Of the five establishments yet to provide full information (197 of 202 establishments have now provided full information), only one has yet to carry out the audit in any form. Where establishments continue not to meet the HTA’s General Directions, options for escalation include directions and licence conditions, followed by the possibility of regulatory action. A balanced decision needs to be taken on whether there are reasonable mitigating factors which can be substantiated.</p> <p>34. Where alterations were made by the HTA to the establishment’s self assessment this was based on information from inspections. It was confirmed that if a deadline for improvement/s is missed then an establishment’s score may be readjusted.</p> <p>35. Overall, the findings of the report are broadly positive. The post-mortem sector continues to have a strong focus on implementing systems that meet regulatory requirements and ensure tissue is kept only with the appropriate consent. This has resulted in a high level of compliance with HTA standards and a low incidence of unauthorised tissue retention. There remain one or two areas of concern, some of which have been put right immediately by establishments, others which will need addressing over a longer timescale.</p> <p>36. An action plan has been developed based on the results of the audit. This should be combined into the Regulatory Activity Report and progress reported via this mechanism.</p> <p>37. Members approved the report for future publication</p> <p>Action: The PM sector action plan to be combined within the Regulatory Activity Report as a mechanism for reporting progress.</p> | <p>AC</p> |

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| Item 10 | Living Organ Donation consultation [paper: HTA (26/11)] | |
| | <p>38. Allan Marriott Smith introduced the paper and explained this had been circulated to IAWG members for comment. In discussion a number of themes emerged:</p> <ul style="list-style-type: none"> i. Consultation at this stage was not suitable. The draft document did not make clear what the focus of the consultation was. There was a need for less focus on technical and procedural issues and more on the key issue of the risk of reward in the context of a world where organ trafficking was a reality in some parts. ii. The review of the year event in July should be a forum for discussion on the issue of less established relationships and the risks they give rise to. It would be of value to have a speaker from the Netherlands to explain the approach taken in directed organ donation between relative strangers there. iii. Any engagement with the sector and public on this matter should focus on the framework we are seeking to establish and explore relationships formed via social media and more distant relationships. iv. Members concluded more work was needed before conclusions could be drawn on a possible consultation exercise. <p>Action: A discussion paper to be drafted for the Members' Group meeting on 28 June setting out proposals for next steps.</p> <p>Action: A speaker from the Netherlands to be secured for the review of the year event.</p> <p>Action: An interim practical guidance note to be drafted for cases of this nature.</p> | <p>AMS</p> <p>SG</p> <p>AMS</p> |
| Item 11 | Regulatory Activity Report 1 January to 31 March 2011 [paper: HTA (27/11)] | |
| | <p>39. Alan Clamp introduced the paper, which was in a new format developed by the Regulation Members' Group.</p> <p>40. Members welcomed the clarity of the report and noted that there were occasional delays in reporting serious adverse events and reactions. The HTA is seeking to provide further information to relevant sectoral groups (e.g. British Association for Tissue Banking) on what qualifies as "serious" and the importance of timely reporting.</p> <p>41. Freedom of Information requests may be made based on information in the report and a balance must be struck</p> | |

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| | <p>between providing information as required and protecting the families involved.</p> <p>42. The Authority noted the contents of the paper.</p> <p>Action: Issues around Serious Untoward Incidents and Freedom of Information Requests to be discussed at the next Regulation Members' Group.</p> | AC |
| Item 12 | Summary of post-inspection feedback [paper: HTA (28/11)] | |
| | <p>43. Alan Clamp introduced the paper which gave an overview of post-inspection feedback received over the past year.</p> <p>44. Members noted the generally positive feedback and asked whether anonymous responses tended to be negative. It was thought anonymous responses were due to the design of the form rather than a desire to leave poor feedback: the anonymous responses were equally positive. The move to an online form should prompt a reduction in the number of non-attributable feedback.</p> | |
| Item 13 | Absence of a presumed genetic link [paper: HTA (29/11)] | |
| | <p>45. Allan Marriott Smith introduced the paper which recommended an adjustment to the existing policy position.</p> <p>46. The Authority noted the new policy position and the intention to provide updated guidance to transplant units.</p> <p>Action: A letter to be drafted and sent to transplant units notifying them of the new policy position.</p> | AMS |
| Item 14 | Human Tissue Authority public meeting and Annual Review event update [paper: HTA (30/11)] | |
| | <p>47. Shaun Griffin introduced the paper which set out arrangements for the July public Authority meeting.</p> <p>48. The Chair urged Members to attend the afternoon session in addition to the morning meeting.</p> <p>49. The Authority accepted the paper for information.</p> | |
| Item 15 | Strategic performance review April 2011 [paper: HTA(31/11)] | |
| | <p>50. Allan Marriott Smith introduced the paper and provided further information on the KPI on vacancy rates. This was a new KPI for 2011/12 and seeks to track whether the organisation has the required number of staff to deliver the agreed business plan. 8% of roles are currently vacant against a target of 5%, this equates to 4 roles out of 50.</p> <p>51. Work to establish the confidence of the post mortem sector in our regulation will be delayed until later in the year.</p> | |

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| Item 16 | Financial report April 2011 [paper: HTA (32/11)] | |
| | <p>52. Sue Martin introduced the paper and informed Members that copies of the draft annual report and accounts were available on request.</p> <p>53. The deficit presented in the accounts is due to the credits issued in 2010/11 having been quantified using pre-audit figures which were marginally different from the audited figures. The National Audit Office is content with this and the matter will be discussed at the June Audit Committee meeting.</p> | |
| Item 17 | Any other business | |
| | <p>54. Members noted that a number of public sector bodies have been asked to develop proposals for their contribution to the Big Society agenda. The HTA may be asked to do likewise.</p> <p>Action: Members wishing to sit in on an Independent Assessment as a development activity should contact Victoria Marshment.</p> | All |

The meeting closed at 1.15 pm



Authority paper

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| Date | 26 July 2011 | Paper reference | HTA (34/11) |
| Agenda item | 6 | Author | Shaun Griffin |

ALB review and shared services update

Purpose of paper

1. This paper provides the Authority with a summary of the activities arising from the review of Arm's Length Bodies (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

Background

3. The Authority held its first substantive discussions about the implications of the Department of Health (DH) arm's-length bodies review at its away day on 29 September. Whilst the ALB review proposed that the majority of Human Tissue Authority (HTA) functions transferred to the Care Quality Commission (CQC), some other proposals were tentative (the transfer of tissue and cells for treatment to the Medicine and Healthcare products Regulatory Agency (MHRA), and some were contingent on other decisions (such as the Academy of Medical Sciences (AMS) review of medical research regulation). In some cases, e.g. organ donation and public display, no proposals were made.
4. At the 23 November meeting, the Authority discussed a number of different options for the transfer of functions and what these might mean for the HTA's

governance and management, and stakeholder and staff views on the options. A paper setting out the criteria by which the merits of various options could be judged was discussed at the 25 January Authority meeting. At this meeting, the Authority agreed unanimously that keeping the HTA's functions together as a single entity would best meet the criteria and maintain public and professional confidence in the safe and ethical use of human tissue.

5. Members agreed that in meetings with Ministers and DH, the 'all functions' approach should be vigorously pursued.

Progress in Parliament

6. The Public Bodies Bill, the main legal vehicle by which the Government will implement the ALB Review was introduced in the House of Lords. On 1 February a Grand Committee debate was held, when Baroness Thornton asked Her Majesty's Government "how they will maintain public confidence and patient safety following the abolition of the HFEA [Human Fertilisation and Embryology Authority] and HTA".
7. Three Committee Stage debates were held in the Lords. The first, on 28 February, led to the removal of schedule 7 of the Bill, which allowed the Government to modify the functions or abolish, any of the bodies in the schedule. The HTA remained in schedule 5 which allowed our functions to be transferred, abolished or modified in some other way.
8. In the final committee stage debate on 10 March, Peers debated amendments to remove HTA and HFEA from schedule 5 of the Bill and there was a consensus across all benches that both bodies do an excellent job. The amendments were withdrawn as a result of Ministerial commitments.
9. The HTA and HFEA were debated in the report stage of the Bill on 28 March, and in its third reading, which took place on 9 May in the Lords.
10. Peers debated a number of amendments during the third reading, including three relating to the HTA. They related to changes not being made to the HTA or HFEA's functions without assessment and consultation, and having safeguards in the form of an ethics committee in the new research regulator before any functions are transferred. The amendments that were voted on were narrowly defeated.

11. Earl Howe, the Minister with responsibility for the ALB Review wrote to Baroness Thornton following the report stage. He noted the Government's intention to consult on the options as to where certain functions are best transferred. In the third reading debate, he said that having taken into account the strength of feeling expressed in the debates, the Government's preferred option was to transfer the HTA and HFEA's functions to the CQC, with the exception of certain research-related ones. At present those research functions proposed to transfer are HFEA functions. None relate to the HTA.
12. The debate proved very helpful in extending and firming up commitments from the Minister about the future of the HTA and HFEA. Earl Howe reiterated the point that the transfer of functions would take place at the same time rather than having to go through a series of changes.
13. Earl Howe also said the Government would undertake a full impact assessment. This would include a view about the cost-effectiveness of the Government's proposals.
14. The Bill has since passed to the House of Commons. During the second reading debate, held on 12 July, an amendment was tabled by the opposition to decline a second reading because they believed it failed to provide a full and comprehensive plan for reform of public bodies.
15. The debate focused on concerns relating to issues including the Chief Coroners Office, the Equalities and Human Rights Commission, and Regional Development Agencies. The main themes were around the cost of any reforms and concerns around the people and workforce.
16. The amendment was declined and the Bill will now pass to the Committee Stage, which is expected to take place in September/October.

Views from stakeholders

17. On 4 February, Diana Warwick wrote to selected new public groups seeking their opinions.
18. Diana met members the public affected by past events, David Thewlis and Stuart Taylor. Roger Goss and Joyce Robbins from Patient Concern have also communicated their concerns in relation to informed consent.
19. Professors of Medical Law, Margaret Brazier, David Price and Jean McHale voiced concerns about the future of the HTA in a letter to the Sunday Times on 20 February.

20. In a letter to the Guardian, consultant transplant surgeons Nizam Mamode, Vassilios Papalois, Keith Rigg and Christopher Watson, expressed their disquiet about the proposed dismantling of the HTA.
21. A subsequent Observer feature article on altruistic organ donation highlighted concerns amongst and peers, MPs and doctors that the HTA's organ donation work will be damaged.

Meeting with officials to discuss the HTA's research functions

22. Senior Management Team members met officials from our DH sponsor branch and the Research and Development Directorate responsible for taking forward the work on the Health Research Authority (HRA), which was recommended by the AMS review. The aim of the meeting was to discuss the future of the HTA's research functions. The DH officials accepted the case for keeping responsibility for regulating the storage of tissue for research alongside our other functions.
23. They concluded that advice and guidance on storage of tissue for research should stay with our functions. The DH's key concern was that there was a seamless 'front end' for researchers, with clear information on the various pathways through the approval processes, with support to help them navigate the system. The HRA would have a role in pulling together a clear and comprehensive system for all aspects of the approvals and regulation processes for health research. Officials were confident the HTA would be able to play an active role in developing comprehensive guidance because of our strong track record in working collaboratively to support researchers.
24. Although this outcome is not guaranteed, as Ministers have yet to approve this approach, there is every reason to believe that DH's preferred approach in proposed consultation later in the year would be to keep the HTA functions, including research, together and transfer them to the CQC.

Timing

25. Further primary legislation will be needed to give a statutory basis for the Health Research Authority (which the Government has said will be in place before any transfers are made) and to give ministers the powers to abolish the HTA and HFEA (which were removed from the PBB in the Lords).
26. The consultation on the HTA and HFEA's functions is expected to take place later in the year.
27. The DH's judgement is that any transfer of functions is likely to take place in 2014. In light of recent developments this may prove ambitious. In the

meantime we are working increasingly closely with CQC, HFEA and on the shared services agenda.

Developments with CQC and HFEA

28. The Authority paper on 24 May 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 have 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.

Shared services

29. The DH's Business Shared Services Transition (BSST) programme aims to streamline the provision of "back office" functions in DH and all its ALBs by the use of shared service centres, centrally negotiated contracts for all to use and more collaborative working. The BSST Programme is expected to make significant efficiency savings.
30. The parts of the programme that could have the most impact on the HTA are finance and HR. More details about these are provided below.
31. There is likely to be scope to benefit from central contracts and collaborative working in the areas of legal advice, communications and other procurement. The HTA is likely to be required by end of year to use DH contracts for office supplies, temporary contractors and external legal advice. Collaborative working, in particular on legal advice and communications, is being explored. A meeting of ALB Communications Directors and the Director General responsible for the ALB transition programme is being held at the end of July. However, DH recognise the central role of strategic communications as sovereign to organisations.
32. Estates and customer services proposals are unlikely to have significant impact on our work. Our move to 151 Buckingham Palace Road has already delivered the changes proposed on estates. Customer service proposals are less relevant to the HTA as we receive relatively small number of enquiries and requests for information.

Finance

33. DH has approved the business case that was submitted by the BSST programme to proceed to more detailed planning for moving to a shared service centre. The next steps will involve engaging key ALB staff in working with the shared service business provider in carrying out detailed impact and risk assessments.
34. The HTA will not be engaged separately – we are being considered as part of CQC's transition. CQC move to shared services in October and when that is in place, CQC will start to explore transition for the HTA.
35. In preparation, HTA finance staff attended an open day run by the shared service provider in Leeds. This explained the services that would be provided and gave attendees an opportunity to see where and how work would be carried out. The service is well organised and would be beneficial to organisations with a large number of transactions. The HTA remains to be convinced that this is a cost effective and efficient service with our smaller level of business and will explore this with CQC later in the year.

HR

36. DH has concluded that a completely shared service model would not release sufficient savings. All the options for a more collaborative model will be proposed in the Outline Business Case due to be completed by the end of July. Our aim is to work more closely with the CQC and HFEA to find efficiencies by sharing services. We are looking at systems and processes to see where this can be achieved. This will start with transactional services such as payroll, and will include other areas such as training courses.

Summary

37. In summary, the Authority's ambition of keeping all our functions together, discussed in January, appears to have won Governmental support. This is good news for public confidence in the safe and ethical use of human tissues and organs, and should give greater reassurance regarding the retention of expertise and for the future of HTA staff. In the meantime we are working closely with other regulators to minimise impact of regulation, and seeking to implement the shared services agenda. We are also making further efficiencies for the 2012/13 financial year which will be reported to the Authority in September.



Authority paper

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| Date | 26 July 2011 | Paper reference | HTA (35/11) |
| Agenda item | 7 | Author | Alan Clamp |

Update on the implementation of the European Union Organ Donation Directive (EUODD)

Purpose of paper

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

Background

2. 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.
3. Over the next few months the HTA will be working with the Department of Health (DH) on the drafting of the Statutory Instrument (Regulations) that will transpose the Directive into UK law. The HTA will also be developing a set of Directions which will set out the requirements that must be met to ensure compliance with the Directive.

The HTA project for implementing the ODD

4. The HTA project plan for implementation includes five main areas of work, each of which consists of between one and four discrete work packages (WP; see Annex A).

(a) Information for the sector:

- WP01 – influence and contribute to the drafting of the Statutory Instrument by the Department of Health
- WP02 – publish Directions to support the Statutory Instrument (including public consultation on the draft Directions) and provide operational detail to licensed establishments
- WP03 – manage stakeholder engagement workshops
- WP04 – develop licensing standards for the organ donation and transplantation sector.

(b) HTA licensing:

- WP05 – develop internal processes, systems and staff training to support licensing and regulation of the sector
- WP06 – update Customer Relationship Management (CRM) systems for licensing the new sector
- WP07 – develop a fees model in consultation with stakeholders

(c) NHSBT assisted functions:

NHS Blood and Transplant (NHSBT) is already carrying out a number of functions required by the ODD. These functions relate to data capture and retention, the role of NHSBT as a European Exchange Organisation, the reporting and management of serious adverse events and reactions (SAEARs), and the annual reporting of activities related to donation and transplantation.

Under the proposed arrangements for assisted functions, NHSBT would continue to perform these roles but the HTA as the Competent Authority would retain the ultimate responsibility, and be held accountable for the successful provision of these functions. Arrangements need to be in place between HTA and NHSBT to allow the HTA to discharge its accountability effectively.

- WP08 – determine the roles and responsibilities of HTA and NHSBT
- WP09 – determine the roles and responsibilities for capturing information and managing SAEARs.

(d) Audit programmes:

- WP10 – identify interfaces with other regulators and accrediting bodies required for the efficient and proportionate implementation of the ODD
- WP11 – develop an HTA audit/inspection programme.

(e) External training:

- WP12 – develop and implement training workshops for Designated Individuals (DIs).

Project governance

5. The HTA has an internal ODD Governance Group (ODDGG) which is chaired by the Director of Regulation and has representation from all four Directorates in the HTA. The group meets weekly to review progress on the HTA implementation plan, to manage risks and to agree the actions required to keep the project on track.
6. An ODD Steering Group, chaired by the Department of Health, and including a range of stakeholders in the organ donation and transplantation sector, meets monthly to review progress against the UK's overall ODD implementation plan.

Key future milestones

- Twelve week public consultation on the Regulations and Directions: September to November 2011
- Stakeholder engagement workshop on managing serious adverse events and reactions: October 2011
- Revised Regulations and Directions: December 2011
- Licensing fees announced: December 2011
- DI training workshops: January and 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

7. 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.

Risk management

8. The key risks and associated mitigating actions associated with implementing the ODD are outlined below.

(a) **Insufficient staff resource available to carry out the work in the required timeframes.**

This is being mitigated by: recognising the ODD has a high priority project; ring-fencing the time of project team members; reviewing business plan objectives to seek any flexibility in timing or scope; making best use of synergies with partner organisations, such as DH and NHSBT; succession planning for

members of the ODD Project Team; and obtaining additional financial resources from DH.

(b) **Regulatory framework is not fit for purpose and/or not deemed to be necessary by the transplant sector.**

This is being mitigated by: regular communication and stakeholder engagement with those involved in the organ donation system; seeking specialist advice on all aspects of the donation process; liaison with the EU and other Competent Authorities; and through the formal public consultation process.

(c) **The deadline for ODD implementation is missed.**

This is being mitigated by: robust project governance and project management; regular reviewing, updating and reporting of project plans; agreement of milestones and deadlines with key partners; ensuring that all partners are aware of the risks and implications of missing the August 2012 deadline for implementation.

(d) **IT systems required for effective implementation are not fit for purpose and/or are not completed on time.**

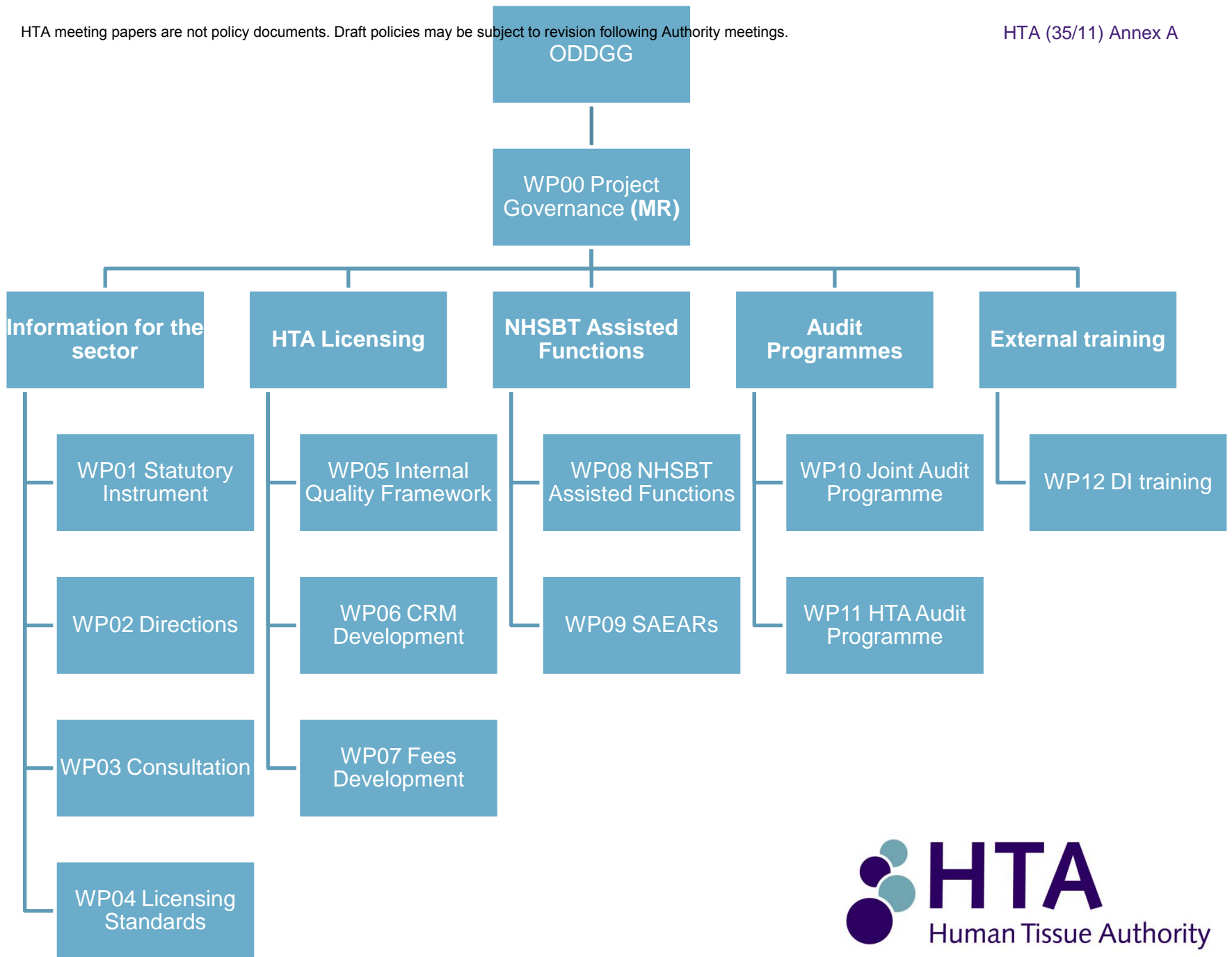
This is being mitigated by: setting up an IT working group to consider the requirements for licensing, fees and reporting SAEARs; obtaining additional funding for the development of IT systems from DH; and having in place a contingency IT plans.

(e) **Insufficient funding available to implement the regulatory framework**

This is being mitigated by: the efficient running of the ODD project; seeking efficiencies by working in partnership with DH and NHSBT; making use of ODD funds held by DH for stakeholder engagement; and securing additional funding from DH.

Actions for the Authority

9. Members are asked to note the content of this report.





Authority paper

| | | | |
|--------------------|--------------|------------------------|-------------|
| Date | 26 July 2011 | Paper reference | HTA (36/11) |
| Agenda item | 8 | Author | Alan Clamp |

Regulatory Activity Report 1 April to 30 June - Executive Summary

Purpose of paper

1. This paper provides an executive summary of the latest quarterly Regulatory Activity Report (RAR). The full version of the RAR was approved by the Regulation Member's Group on 13 July 2011 and is supplied as an appendix to this short paper.

Executive summary

2. The Regulatory Activity Report (RAR) summarises the management of critical shortfalls, investigations, legal activity and serious incidents reported to the HTA. The latest RAR also includes a section on other regulatory activity undertaken by the HTA during the first quarter of 2011/12.
3. No critical shortfalls against standards have been identified since the grading criteria were changed in November 2010.
4. Three investigations were undertaken in the first quarter of 2011/12; one has been resolved and two are ongoing.
5. One Regulatory Action Panel was convened during the quarter and recommended a non-routine inspection of the establishment concerned. This inspection will take place in October 2011.
6. Three non-routine inspections took place during the first quarter of the business year, none of which resulted in significant regulatory action.

7. No legal notices were issued during quarter one of 2011/12 and there were no representations or appeals.
8. Twelve Serious Untoward Incidents (SUIs) were reported in the first three months of 2011/12, four fewer than in the previous quarter. Eleven of these are still being investigated. All but two of the SUIs reported in previous quarters have now been investigated and closed.
9. Twenty-four Serious Adverse Events and Reactions (SAEARs) were reported in the first quarter of 2011/12, compared with 29 in the previous quarter. Most of the SAEARs reported in quarter one are still undergoing follow-up and assessment. HTA staff continue to work with the patient treatment (Human Application) sector to raise the profile of reporting SAEARs in a timely manner. The average time taken to report SAEARs after discovery is reducing, but this remains an area for further improvement.
10. The final section of the RAR describes the escalation of regulatory activity at one establishment and provides a summary of the actions taken following the audit of post mortem establishments that took place in 2010/11.

Action for the Authority

11. Members are asked to note the contents of this report..

Authority paper

| | | | |
|--------------------|--------------|------------------------|----------------------|
| Date | 26 July 2011 | Paper reference | HTA (36/11) Appendix |
| Agenda item | 8 | Author | P Bhattacharyya |

Regulatory Activity Report 1 April 2011 to 30 June 2011

1. This paper provides a high-level summary to the Authority of how the Human Tissue Authority (HTA) manages information relating to actual or potential breaches of the regulatory framework, both internally and externally. This report provides information on:
 - a. **Critical shortfalls:** any critical shortfalls identified against licensing standards;
 - b. **Investigations:** how the HTA deals with information it receives about breaches, including investigation of allegations from external sources, regulatory action panels convened, and management of information through routine and non-routine inspections;
 - c. **Legal activity:** legal activity associated with the management of breaches, including issuing legal notices and responding to requests to hear representations/appeals;
 - d. **Incidents:** serious incidents routinely reported to the HTA from licensed establishments in the post mortem and human application sectors; and
 - e. **Other regulatory activity:** this new section of the report describes regulatory activities undertaken by the HTA which fall outside of categories (a)-(d) above. This could include, for example, measures which are taken to address failures to comply with General Directions, or taken as a result of repeated regulatory breaches by an establishment. It also includes information on the Post Mortem Audit action plan.

Critical shortfalls

2. The grading of shortfalls against licensing standards as minor, major or critical began on 1 November 2010. Shortfalls are assessed by a Regulation Manager using pre-defined criteria following a site-visit inspection. Critical shortfalls are those considered to be of such significance that the HTA would normally expect licensable activities to cease immediately until that shortfall was addressed. Major or minor shortfalls normally require a Designated Individual (DI) to advise the HTA on how the shortfalls will be addressed over longer timeframes.
3. No critical shortfalls were reported in 2010-11 following site visit inspections. In quarter one (Q1), no critical shortfalls were identified following a site-visit inspection.

Investigations

4. Three investigations were carried out in Q1:
 - a. An allegation was received from a professional working at a licensed establishment that another establishment was importing and storing tissue for human application (patient treatment) without the appropriate HTA licence. The HTA investigated and found that the establishment was not, in fact, carrying out the alleged activities. No further regulatory action was deemed necessary.
 - b. Information was received from a member of the public regarding the temporary misplacement of documentation (now found) given by them to an overseas office of a Human Application (HA) establishment. The HTA is reviewing the establishment's information protection policies.
 - c. Information was received from a member of the public concerning cord blood cells which had been procured in 2006. Since then, the complainant has been unable to trace where the cells are in storage. The complainant understood the cells are being stored in another EU member state. We are seeking further information in relation to this issue.
5. Following an investigation in quarter four (Q4) of 2010-11, an establishment which had previously carried out the unlicensed import and distribution of tissue for human application has ceased these activities. The establishment intends to apply for an HTA licence so it may carry out these activities legally in the future. There are no other ongoing investigations.
6. A sector-specific breakdown of investigations carried out during the past five quarters is given in Table 1.

| | Human Application | Post Mortem | Public Display | Research | Anatomy |
|----------|-------------------|-------------|----------------|----------|---------|
| 11/12 Q1 | 3 | 0 | 0 | 0 | 0 |
| 10/11 Q4 | 3 | 0 | 0 | 0 | 0 |
| 10/11 Q3 | 2 | 0 | 0 | 0 | 0 |
| 10/11 Q2 | 0 | 0 | 0 | 0 | 1 |
| 10/11 Q1 | 5 | 0 | 0 | 0 | 1 |

Table 1: Numbers of investigations

Regulatory Action Panels (RAPs)

7. One RAP was convened in Q1.

- a. An HA establishment does not appear to be making sufficient progress in meeting 13 additional conditions which were placed on the licence following a routine site visit inspection in April 2010. A RAP was convened, the outcome of which will be to carry out a non-routine inspection to assess progress being made against the additional conditions, and to confirm that the DI is fulfilling his statutory responsibility to ensure suitable practices take place.

8. A sector-specific breakdown of RAPs convened during the past five quarters is given in Table 2.

| | Human Application | Post Mortem | Public Display | Research | Anatomy |
|----------|-------------------|-------------|----------------|----------|---------|
| 11/12 Q1 | 1 | 0 | 0 | 0 | 0 |
| 10/11 Q4 | 1 | 0 | 0 | 0 | 0 |
| 10/11 Q3 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q2 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q1 | 3 | 0 | 0 | 1 | 0 |

Table 2: Numbers of RAPs

Non-routine inspections

9. Three non-routine (announced) site-visit inspections took place in Q1:

- a. The HTA and Medicines and Healthcare products Regulatory Agency (MHRA) conducted a joint inspection of an HA establishment prior to its move into new premises. The MHRA routinely inspects new premises

shortly before the completion of construction, which dictated the timing of this inspection. The HTA inspector gave advice to the establishment on meeting quality standards relating to premises and facilities, and discussed some of the proposed changes to quality documents. Construction work on the premises was still in progress at the time of the inspection. No regulatory action by the HTA was deemed necessary at this time. Another HTA and MHRA joint inspection will be scheduled when the establishment has moved into the new premises.

- b. An HA establishment was inspected to determine the suitability of the proposed facilities to carry out a new licensable activity, and to verify other recent changes to the licence. Some shortfalls were identified at the inspection, and to address these the establishment will be required to develop a Corrective and Preventive Action (CAPA) plan.
 - c. A Post Mortem (PM) establishment was inspected following completion of the internal investigation of a serious untoward incident (SUI) in Q4 of 2010-11, in order to satisfy the HTA that all risks of a similar incident recurring had been mitigated. The SUI was given a 'high' rating by the HTA due to the establishment's initial poor investigation of the incident. The HTA provided advice to the establishment about the investigation of the SUI prior to the inspection in Q1 of 2011-12. The inspectors found the establishment had subsequently carried out a full root cause analysis of the SUI, that robust procedures had been put in place to prevent a recurrence, and that SUI reporting systems were now in place. No further regulatory action was deemed necessary.
10. As described in the Regulatory Activity Report (RAR) for Q4 2010-11, serious concerns relating to consent standards were identified at the routine site-visit inspection of an HA establishment in Q4 of 2010-11. A RAP was held after the inspection, and Special Directions were issued to the establishment to address the shortfalls against these standards. A follow-up non-routine inspection will be scheduled for quarter two (Q2), the findings of which will appear in a future RAR.
11. A sector-specific breakdown of non-routine inspections carried out during the past five quarters is given in Table 3.

| | Human Application | Post Mortem | Public Display | Research | Anatomy |
|----------|-------------------|-------------|----------------|----------|---------|
| 11/12 Q1 | 2 | 1 | 0 | 0 | 0 |
| 10/11 Q4 | 1 | 0 | 0 | 0 | 0 |
| 10/11 Q3 | 2 | 2 | 0 | 0 | 0 |
| 10/11 Q2 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q1 | 1 | 2 | 0 | 0 | 0 |

Table 3: Numbers of non-routine inspections

Legal notices

12. No licences were suspended or revoked by the HTA in Q1. A sector-specific breakdown of legal notices issued in the past five quarters is given in Table 4.

| | Human Application | Post Mortem | Public Display | Research | Anatomy |
|----------|-------------------|-------------|----------------|----------|---------|
| 11/12 Q1 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q4 | 2 | 3 | 0 | 0 | 0 |
| 10/11 Q3 | 2 | 0 | 0 | 0 | 0 |
| 10/11 Q2 | 4 | 0 | 0 | 0 | 0 |
| 10/11 Q1 | 4 | 0 | 0 | 0 | 0 |

Table 4: Numbers of legal notices issued

Representations or appeals

13. The HTA received no notifications of intention to make a representation or an appeal in Q1. A sector-specific breakdown of appeals heard during the past five quarters is given in Table 5.

| | Human Application | Post Mortem | Public Display | Research | Anatomy |
|----------|-------------------|-------------|----------------|----------|---------|
| 11/12 Q1 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q4 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q3 | 0 | 0 | 0 | 0 | 0 |
| 10/11 Q2 | 1 | 0 | 0 | 0 | 0 |
| 10/11 Q1 | 0 | 0 | 0 | 0 | 0 |

Table 5: Numbers of appeals heard

Serious untoward incidents (SUIs) reported in the post mortem sector

SUIs reported in Q1

14. Twelve SUIs were reported in Q1, with follow-up investigation reports waiting to be received in the majority of incidents (Table 6).

| Number of SUIs | SUI category | Status |
|----------------|--|------------------------|
| 2 | Accidental damage to a body before or after the post-mortem examination (PME) | 1 ongoing, 1 closed |
| 1 | Any incident that may result in adverse publicity that may lead to damage in public confidence | 1 ongoing |
| 2 | Loss of an organ | 2 ongoing |
| 1 | Major equipment failure | 1 ongoing |
| 1 | Post-mortem examination conducted was not in line with the consent given or the PME proceeded without adequate consent | 1 ongoing |
| 1 | Post-mortem examination of the wrong body | 1 ongoing |
| 3 | Release of the wrong body | 3 ongoing |
| 1 | Serious security breach | 1 ongoing |

Table 6: Numbers of SUIs in the PM sector reported to the HTA in Q1

15. The requirement for PM establishments to report an SUI to the HTA within five working days from the date of its discovery was communicated to the sector through the April HTA e-newsletter. This requirement took effect from 6 April 2011.

16. Of the 10 SUIs which took place after 6 April, seven were reported to the HTA within five working days, and one was reported six working days after the incident occurred. Two SUIs were reported to the HTA 10 or more working days after the incident had been discovered. The establishments will be reminded of the importance of the five-day reporting requirement. For June, 86% of SUIs were reported within five working days.

17. A breakdown of SUIs reported by category during the past five quarters is given in Table 7. The most common shortfalls identified as contributory factors to SUIs reported to the HTA, and the corrective actions taken to prevent recurrence of these incidents, are captured in the *HTA Post mortem sector report June 2011*, published on the HTA website on 7 July.

| | 11/12 Q1 | 10/11 Q4 | 10/11 Q3 | 10/11 Q2 | 10/11 Q1 |
|---|-------------|-------------|-------------|-------------|-------------|
| Accidental damage to a body before or after post-mortem examination | 2 | 1 | 2 | 1 | 3 |
| Any incident (not listed elsewhere) that could result in adverse publicity that may lead to damage in public confidence | 1 | 4 | 7 | 3 | 1 |
| Discovery of an additional organ(s) in a body on evisceration for a second post-mortem examination | 0 | 0 | 0 | 0 | 0 |
| Discovery of an organ or tissue following post-mortem examination and release of body | 0 | 2 | 3 | 3 | 0 |
| Disposal or retention of a whole fetus or fetal tissue (gestational age greater than 24 weeks) against the express wishes of the family | 0 | 1 | 0 | 0 | 0 |
| Disposal or retention of an organ against the express wishes of the family | 0 | 0 | 0 | 0 | 0 |
| Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services | 0 | 0 | 0 | 1 | 0 |
| Loss of an organ | 2 | 0 | 0 | 0 | 1 |
| Major equipment failure | 1 | 2 | 0 | 0 | 0 |
| Post-mortem examination conducted was not in line with the consent given or the Post-mortem examination proceeded with inadequate consent | 1 | 2 | 2 | 0 | 0 |
| Post-mortem examination of the wrong body | 1 | 0 | 0 | 1 | 0 |
| Release of the wrong body | 3 | 2 | 2 | 0 | 4 |
| Removal of tissue from a body without authorisation or consent | 0 | 0 | 0 | 0 | 0 |
| Serious security breach | 1 | 2 | 0 | 0 | 1 |
| Total number of SUIs during that quarter | 12 | 16 | 16 | 9 | 10 |

Table 7: Numbers of SUIs in the PM sector reported to the HTA in the past five quarters

Ongoing SUIs from previous quarters

18. An SUI is considered to be closed only when the HTA is satisfied the incident has been thoroughly investigated by the establishment and appropriate corrective and preventive actions have been taken. The HTA would generally expect to receive a copy of the internal investigation report from an establishment within two months of the initial notification. As the HTA is dependent on an establishment's investigation procedures and timelines, some SUIs may be reported and closed in different quarters. This is reflected by the ongoing status for some incidents in Table 6.
19. In Q1, 14 of the 16 SUIs reported in the previous quarter were closed for HTA purposes following assessment of the investigation reports. Of the two ongoing incidents, the departure of an SUI team member from the HTA contributed to a delay in pursuing one overdue investigation report. However, both overdue investigation reports have now been received, and are being reviewed. Two SUIs from quarter three (Q3) which remained open throughout Q4 were closed during Q1, following receipt of satisfactory follow-up investigation reports from the establishments.

Internal procedures for managing SUIs

20. One year after the introduction of the SUI reporting requirement, the SUI team held a review of systems and documentation. Outcomes of this review included refinements of the SUI classifications and the guidance document, and further strengthening of internal arrangements for managing SUI notifications.

Serious adverse events and reactions (SAEARs) reported in the human application sector*SAEARs reported in Q1*

21. Twenty-four SAEARs, of which 22 were SAEs and two were SARs, were reported in Q1 (Table 8), compared with 29 (21 SAEs, eight SARs) reported in the previous quarter. Follow-up investigation reports have been received for approximately half of the SAEARs.

| Number reported | Activity/type of SAEAR |
|-----------------|------------------------|
| 8 | Procurement event* |
| 1 | Processing event |
| 5 | Testing event |
| 1 | Storage event |
| 1 | Distribution event |

| | |
|---|----------------------|
| 0 | End use event |
| 1 | Transportation event |
| 1 | Preservation event |
| 0 | Materials |
| 4 | Other ** |
| 0 | Donor reaction |
| 2 | Recipient reaction |

Table 8: Numbers of serious adverse events and adverse reactions in the HA sector reported to the HTA in Q1. * two SAEs were discovered and were reported following site-visit inspection ** two SAEs related to quality of tissue, two SAEs to thawing and re-infusion events

24 hour reporting requirement for SAEARs

22. With the issue of General Directions to the HA sector in October 2010 (Directions 003/2010), a mandatory requirement was introduced that an initial notification of a SAE or SAR should be given to the HTA within 24 hours of the *discovery* of the event or reaction by the licensed establishment. The new requirement came into effect from 12 November 2010. A new field to capture the date of discovery of the SAE or SAR was added to the online SAEARs reporting form in Q4 of 2010-11. Internal HTA systems to log SAEARs notifications were updated in Q1 to include the date of discovery.

23. Eight SAEARs notifications were received during June 2011. Of these, 50% of notifications were received within 24 hours of discovery, and 100% of notifications had been received within 8 days of discovery. Of the 24 SAEARs reported to the HTA in Q1, the initial notification was received:

- within 24 hours of discovery in eight instances;
- within 14 days of the date of discovery in ten instances;
- within 40 days of the date of discovery in one instance;
- more than 40 days from the date of discovery in five instances. Of these, two SAEs were reported by one establishment following their discovery during a routine site-visit inspection.

24. Of the incidents reported within 24 hours of discovery, three SAEs had taken place more than one hundred days prior to the date of discovery. Work with the HA sector is ongoing to ensure the reporting requirement is more rigidly adhered to.

- a. During inspections, the HTA will review an establishment's SAEAR reporting Standard Operating Procedure (SOP);
- b. HA establishments receive a site-visit inspection every two years;
- c. The *2009-10 summary report of performance against HTA standards for all sectors*, available from the HTA website, also explains the new requirement.

25. Some SAEs reported in Q1 related to problems with collection bags sourced from one manufacturer. The HTA has contacted the manufacturer for further information and will, if necessary, notify MHRA.

Ongoing SAEARs reported in previous quarters

26. One SAE reported in Q3 of 2010-11, and one SAR reported in Q4, were closed in Q1, following the receipt of additional information from the establishments. With one exception, described in paragraph 27, all SAEARs reported in 2010-11 are now closed.

27. One SAE reported in Q2 of 2010-11 remains open. While follow-up information and details of corrective actions to prevent recurrence of such an event have been received and assessed as satisfactory, a validation study being undertaken as part of the internal investigation will not be available until the establishment commences testing activity later this year. The case will be closed following completion of that study.

Other regulatory activity

28. This new section describes regulatory activity undertaken by the HTA which falls outside categories (a)-(d) in paragraph 1. An example where repeated regulatory breaches by a PM establishment have led to escalation of HTA sanctions is given in paragraphs 29-31. Regulatory actions which were taken based on the findings of the PM audit required by General Directions 001/2010 appear in paragraphs 32-34.

Escalation of regulatory action

29. During a routine site-visit inspection of a PM establishment in late 2009, consent practices were found to have not fully met HTA regulatory requirements. To address this, additional conditions were placed on the licence following the inspection. However, the establishment failed to comply with the additional conditions by the deadlines set by the HTA. The DI subsequently failed to submit promptly a self-assessment of how quality standards were being met, and an audit of retained PM tissue, as required by Directions 001/2010. This repeated failure by the establishment to comply with the HTA's regulatory requirements over a prolonged period led to the scheduling of a non-routine site-visit inspection for Q3 of 2010-11.

30. During the non-routine inspection, it was identified that consent standards remained unmet. A CAPA plan was developed to address these shortfalls. Additionally, whilst the DI was deemed suitable, the HTA recommended that the DI be replaced by someone in a better position to effect change in relation to the licence. While some progress towards addressing the shortfalls was made by

the new DI in the months following the inspection, the shortfalls were considered to be only partially met by the dates given in the CAPA plan.

31. The HTA escalated its regulatory sanctions to ensure that all appropriate actions needed to meet standards are fulfilled. The HTA wrote to the DI and Corporate Licence Holder contact in June 2011, to:

- set a 30-day deadline (by 18 July) for the submission of evidence which demonstrates that all consent standards are fully met;
- strongly recommend the establishment suspend consented PM examinations until a documented consent procedure is in place and all staff who take consent for PM examinations have attended documented consent training;
- advise that if all consent standards were not fully met by the 30-day deadline, the HTA would consider a regulatory suspension of consented PM examinations; and
- work with the new DI to agree new deadlines for meeting the minor shortfalls identified during the non-routine inspection. This was intended to support the new DI who had set the deadlines before she had a full understanding of the role and the shortfalls (she was not in post at the time of the inspection in November 2010).

An update on developments at this establishment will be communicated in the next quarter's RAR.

PM Audit action plan

32. General Directions issued to the PM sector in April 2010 (Directions 001/2010) required the completion of an audit of retained PM material. The audit included an inventory of all currently retained whole organs, wet tissues and fetuses / fetal tissue, and an audit of a proportion of cases where tissue was made into blocks and slides. Audit reports were received from 201 establishments.

- Despite repeated follow-up communications, one establishment failed to complete the audit by the 30 September deadline, due to unforeseen staffing issues.
 - A final deadline of 15 July 2011 has been given in a letter from the Director of Regulation and, depending on the response of the DI, an inspection will be scheduled to take place by end of Q3.
- One establishment submitted the audit significantly late (January 2011) with no explanation from the DI.
 - The establishment was inspected in November 2010 as there were other serious concerns about the establishment; these are now being addressed through the CAPA process (paragraphs 29-31).
- Three establishments completed the audit incorrectly.

- These were required to repeat the exercise to a new deadline and each submitted a new audit report in May 2011. No concerns were raised by these new audits.
 - 59 establishments provided unclear information due to how the report was filled out.
 - Follow up with these establishments to clarify the information was completed during February 2011. All issues were fully clarified.
 - 31 establishments provided information about their records and documentation that caused concern about possible inappropriate retention of tissue. Follow up with these establishments was completed during April 2011 and, in the majority of cases, there was no inappropriate retention. However:
 - Six establishments discovered problems with documentation in eleven coronial cases. Once these cases were identified during the audit, they all took immediate action to resolve the cases.
 - One establishment was determined to have retained material inappropriately in six coronial cases. Once this was identified by the audit, the material was immediately disposed of in an appropriate manner.
33. When all follow up was completed, new risk assessments were carried out for each establishment in order to inform inspection scheduling for 2011-12. All available information was considered in determining a risk rating for each establishment, including:
- the audit findings and the self assessment submitted to the HTA in June 2010 (which provided evidence of how the establishment is meeting the HTA quality standards);
 - the date of its previous inspection (before or after the block and slide audit period of 1 July 2008 – 30 June 2009);
 - previous inspection findings;
 - the communications record;
 - SUIs since the previous inspection;
 - allegations and investigations since the previous inspection;
 - changes to the licence: change in DI or premises (e.g. extension of licence, refurbishment) since the previous inspection.

Higher risk: The establishment was considered to be at higher risk of breaching the regulatory requirements (either licensing or quality standards) and re-inspection was prioritised for Q1 of 2011-12.

Medium risk: The establishment was not considered higher risk but there was evidence to suggest that a breach of the regulatory requirements was possible. Re-inspection was prioritised for Q2 of 2011-12.

Note that for higher and medium risk establishments, follow up had given assurance that concerns raised during the audit had been sufficiently acted upon. Prioritisation for inspection was based only in part on the audit findings.

Low risk: The only concerns about these establishments related to the audit findings and were considered to be minor, i.e. no serious risk of a breach of the regulatory requirements and able to be addressed remotely (i.e. not requiring inspection).

- i. Although considered low risk overall, some establishments received individually tailored advice.
 - ii. The remaining establishments did not require individually tailored advice but will benefit from targeted sector-wide communications.
- The establishment which failed to submit an audit will be scheduled for inspection by the end of Q3.
 - The establishment which submitted its audit significantly late was re-inspected in Q3 of 2010-11. This inspection was immediately carried out as there were other serious concerns about the establishment (paragraphs 28-30).
 - Three establishments were considered to be higher risk and were prioritised for inspection; all three inspections were carried out in Q1 (paragraph 34).
 - 23 establishments were considered to be medium risk and have been prioritised for inspection in Q2. All of these inspections have been scheduled.
 - The remaining establishments are considered low risk and will be inspected by the end of 2011-12.

34. Of the three higher risk establishments inspected in Q1 of 2011-12:

- Establishment A: it was confirmed that all cases in the audit where inappropriate retention had been identified were resolved. An extended audit trail was carried out to provide assurance of the robustness of the current traceability systems. The establishment was found to fully meet all HTA quality standards, with the exception of a consent policy, which is in draft form and needs to be ratified (a minor shortfall). Five pieces of advice were offered against the standards relating to consent, traceability and disposal.
- Establishment B: this establishment was found to fully meet all standards with the exception of the lack of a systematic approach to ensuring timely communications are sought from the Coroner (a minor shortfall). It should be noted that no cases of inappropriate retention were identified as having resulted from the problems with communications about coronial cases.
- Establishment C: this establishment was found to have implemented a new traceability system for all PM material, and was fully meeting all HTA standards, as well as demonstrating several examples of good practice.

Conclusion

35. Members are asked to note the content of this report.



Authority paper

| | | | |
|--------------------|--------------|------------------------|----------------------|
| Date | 26 July 2011 | Paper reference | HTA (37/11) |
| Agenda item | 9 | Author | Allan Marriott Smith |

Framework for living organ donation assessment

Purpose of paper

1. To set out the first draft of a revised process for living organ donation assessments, as described by Authority Members at a meeting of the Policy Members' Group on 28 June 2011.
2. To set out the key milestones in the draft project plan to deliver a solution during the 2011/12 business year as agreed in the HTA strategic plan.

Action

3. The Authority is asked to approve the approach set out in this paper.

Background

4. The Human Tissue Authority (HTA) has a number of responsibilities in relation to the assessment of living organ donation applications. Among these, it is responsible for ensuring 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.
5. Based on its experience of regulating this area, the Authority has expressed concern that the risk of reward may be increased in 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. It has also noted that the risks of duress and coercion will differ on a case by case basis.

6. The Authority has agreed to undertake further work to put in place a framework for deciding which cases are higher risk and should therefore be assessed by a panel of Members, and how these higher risk cases should be assessed. In the strategic plan the Authority committed to a new process being introduced during the current business year.
7. At a meeting of the Policy Members' Group on 28 June 2011, Members described a process which they believed could be used to mitigate these risks and to deliver a framework for the assessment of living organ donation cases which is both transparent and proportionate.

Proposed process

8. Although not formally identified as such, the discussion at the Policy Members' Group implied a set of criteria for any new process. These are set out below, and should guide the design of any new system:
 - The process should be transparent, so that all of those involved can be clear on how the assessment will be managed;
 - There should be limited change to those elements of the process which are already considered fit for purpose;
 - There should be greater scrutiny of those cases where the risk of reward, duress or coercion are judged to be increased;
 - The changes should not put undue additional burden on Independent Assessors (IA), or introduce unnecessary additional costs;
 - No process can guarantee the absence of reward, duress or coercion, but it must demonstrate that the Authority has adequate assurance that these are not factors in the donor's decision to donate.
9. Annex A ***Living Donation Assessment Process – To Be Version 0.1*** describes the process discussed at the Policy Members' Group meeting. For comparison purposes, the existing process is described in Annex B ***Living Donation Assessment Process – As Is***.
10. The new proposed process has a number of new processes and requirements not included in the 'As Is' model:
 - i. Screening
 - ii. HTA risk assessment process;

- iii. Enhanced investigation process;
- iv. Investigation report;
- v. Signed statements.

Screening

11. This step aims to ensure that the application is lawful (there is no obvious indication of reward or duress/coercion) before it enters the formal assessment process. In the 'As Is' process, this step is currently undertaken as part of the panel or executive assessment process. This is a separated in the 'To Be' system to avoid unnecessary formal risk assessment of any cases where the application is unlawful.

HTA risk assessment process

12. At the heart of the new procedure is a more formalised approach to risk assessment. The evaluation of risk is already an implicit part of the assessment of living organ donation cases, but this approach makes the assessment explicit. This assessment would be undertaken by the HTA Executive. This proposal suggests a risk matrix which will allow higher risk cases to be identified and to be filtered through for enhanced investigation prior to an assessment of the case by a panel of three Authority Members.
13. Annex C provides an example of how a points-based system could be applied to identify which cases would require more detailed investigation. The key features of such a system are:
 - **inherent risk score** - which allows the Authority to build in its previous regulatory experience and policy positions into the system. For example, by allocating a low inherent risk score to close genetic relationships, the Authority would be able to reflect the fact that the existing IA process already picks up and eliminates cases where there are concerns about duress and coercion. Similarly, by allocating a higher inherent risk score to cases where, for example, the donor is non-UK based and there is no pre-existing relationship between donor and recipient, the Authority can factor in the policy position that it would want increased scrutiny of such cases.
 - **points-based system for additional risk factors** – which allows for additional scrutiny of those cases where additional risk factors are present. In the example, the additional risk factors considered are: whether the donor and recipient have ever met, whether the motivation of the donor is considered strong, medium or weak (based on the IAs report) and the previous history of altruistic behaviour on the part of the donor.

14. Such an approach will result in a system which does not rely entirely on the type of relationship to decide how and by whom the case is assessed (thus recognising the risks are different from case to case). This approach would also allow the risk scoring to be adapted as experience develops.
15. The Executive would anticipate the need to seek some specialist advice on the development of a robust risk assessment tool and sensitivity testing to establish the likely volume of cases referred to panel under different risk assumptions.

Enhanced investigation process

16. This process has yet to be fully specified, but one early suggestion is that some form of psychological assessment is undertaken in order to get a better view of the donor's motives for donation.
17. Such an approach has parallels with the current psychiatric/psychological assessment for all altruistic donors, although in these cases the assessment is undertaken primarily to establish the mental capacity of the donor. In a new investigation, the assessment may also be required to establish the credibility of the motivation to donate.
18. The Executive has taken initial soundings on this issue and early opinion is that:
 - There seems to be some merit in the concept; assessments could be developed in this way;
 - There are resource issues. limited capacity in NHS budgets which might imply a private solution; and training issues for those involved in the assessment who are unlikely to be familiar with the provisions of the relevant legislation.

Investigation report

19. The report based on the enhanced investigation process which would be used in the panel assessment.

Signed Statements

20. For the higher risk subset of cases, the Authority have proposed that the donor and recipient would also both provide signed statements which set out their

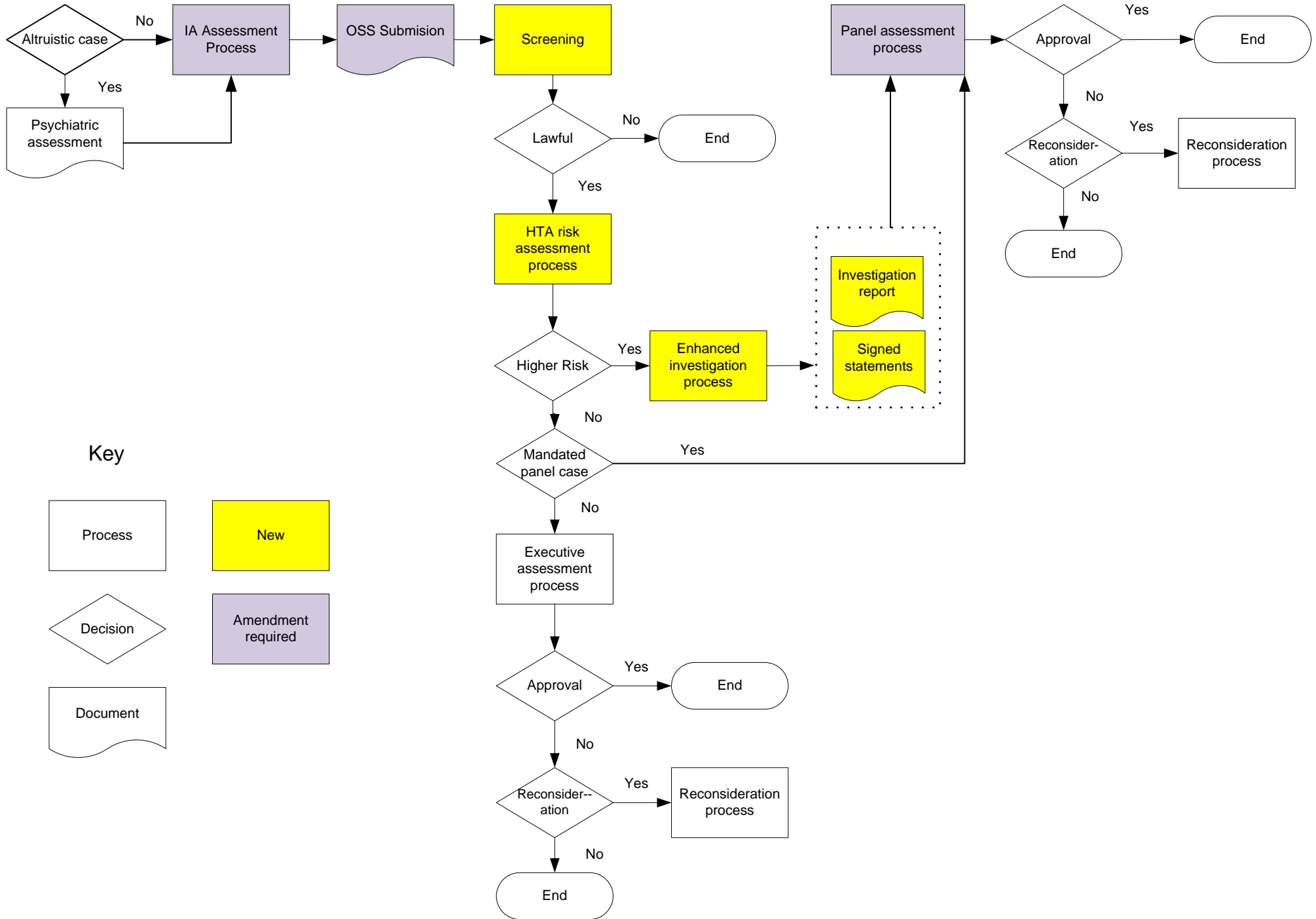
understanding of the law in relation to reward, and the penalties associated with criminal activity of this nature.

Indicative timescales

21. The stages below are indicative timescales required in order to deliver any new process by the end of the current business year.

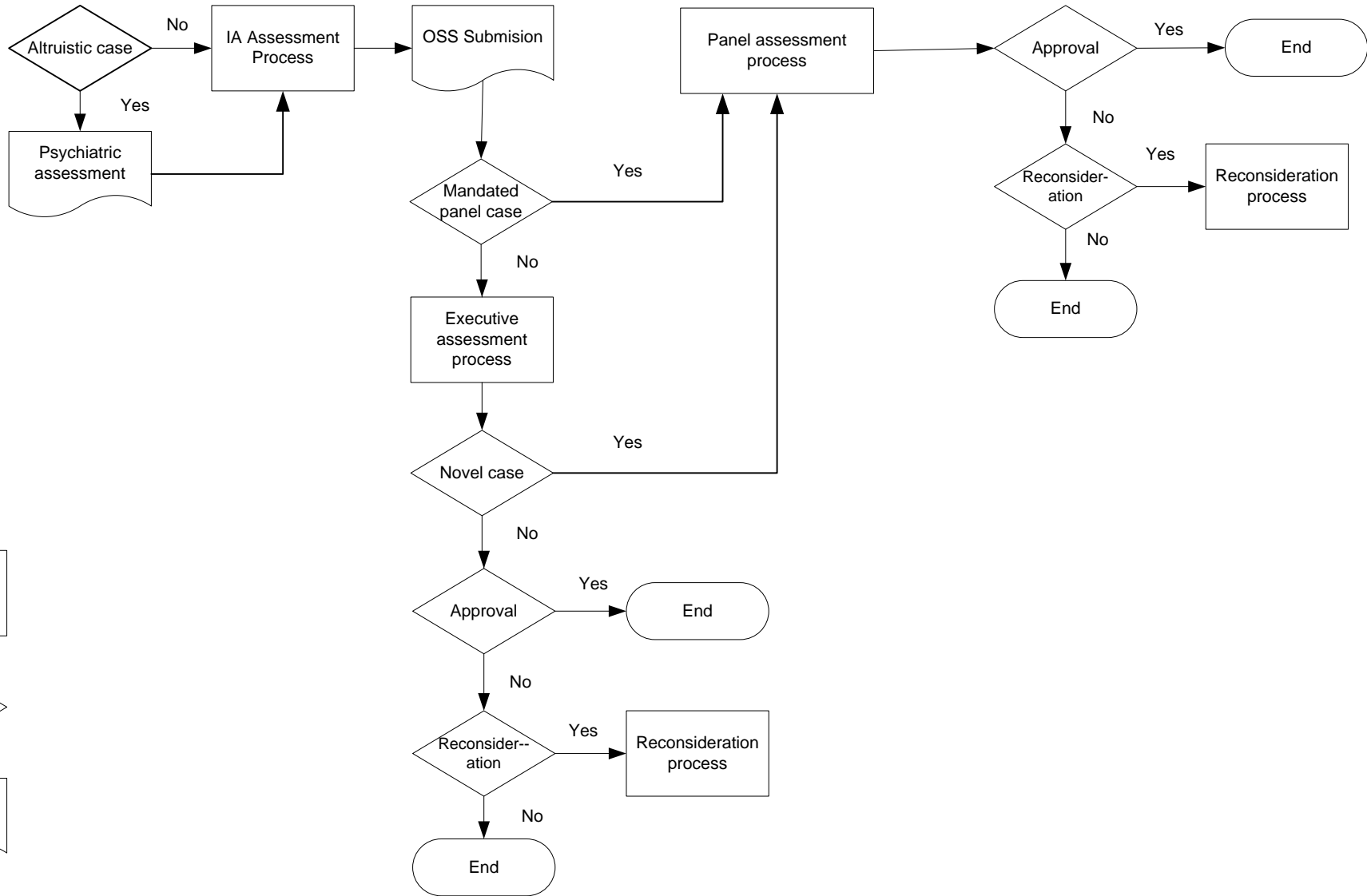
- July to September 2011– process refinement and systems design. Contributions from the annual review event will contribute towards the development of the risk assessment process
- September Authority Meeting - decision on the scope and content of any consultation activity.
- September to December 2011– consultation with the transplant community and more widely if required.
- December 2011 – development of guidance and training.
- January 2012 – adapt specifications based on consultation outcome.
- End January 2012 – finalise guidance and training.
- February 2012 – systems build.
- February and March 2012 - deliver guidance and training.
- April 2012 - system goes live.
- October 2012 – system evaluation.

22. The Executive proposes that the Independent Assessment Working Group continues to oversee this work between Authority meetings.



HTA (37/11) ANNEX B

Living Donation Assessment Process – As Is



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

HTA (37/11) Annex C - Indicative Risk Assessment Framework

| | Inherent risk score | Met | Motivation to donate | | | Altruistic history | | | Adjusted risk score | |
|--|---------------------|------|----------------------|--------|--------|--------------------|------|--------|---------------------|------|
| | | | Yes | Strong | Medium | Weak | High | Medium | Low | Min |
| UK based donor - qualifying relationship (a-g) | 1 | 0 | 0 | 1 | 2 | 0 | 1 | 2 | 1 | 5 |
| UK based donor - other genetic relationship | 1.5 | 0 | 0 | 1 | 2 | 0 | 1 | 2 | 1.5 | 5.5 |
| UK based donor - other pre-existing relationship | 1.5 | 0 | 0 | 1 | 2 | 0 | 1 | 2 | 1.5 | 5.5 |
| UK based donor - no pre-existing relationship | 3 | -0.5 | 0 | 1 | 2 | 0 | 1 | 2 | 2.5 | 7 |
| Non-UK based donor - qualifying relationship (a-g) | 1 | 0 | 0 | 1 | 2 | 0 | 1 | 2 | 1 | 5 |
| Non-UK based donor - other genetic relationship | 2 | 0 | 0 | 1.5 | 2.5 | 0 | 1.5 | 2.5 | 2 | 7 |
| Non-UK based donor - other pre-existing relationship | 2 | 0 | 0 | 1.5 | 2.5 | 0 | 1.5 | 2.5 | 2 | 7 |
| Non-UK based donor - no pre-existing relationship | 5.5 | -0.5 | 0 | 1.5 | 2.5 | 0 | 1.5 | 2.5 | 5 | 10.5 |

In this example any case with an adjusted risk score >5 would enter into the enhanced investigation process.



Authority paper

| | | | |
|--------------------|--------------|------------------------|----------------|
| Date | 26 July 2011 | Paper reference | HTA (38/11) |
| Agenda item | 10 | Author | Jessica Porter |

Report on the living organ donation system January – June 2011

Purpose

1. This paper provides the Authority with an update on the living organ donation programme, specifically the number of reports submitted by Independent Assessors (IAs) to the Human Tissue Authority (HTA) for assessment.

Overview

2. During the last financial year (1 April 2010 to 31 March 2011), the HTA received 1207 cases: the Executive assessed 1099 cases and 108 cases were referred to a panel of Authority Members for decision.
3. This update specifically covers the period from 1 January 2011 to 30 June 2011.
4. A total of 588 cases were submitted between January and June. Of these, the executive assessed 532 cases and a panel of Members assessed the remaining 56.
5. Eighty-seven per cent of cases were fit for purpose at the point of submission, against a target of 75%

Summary of cases 1 January to 30 June 2011

| | Total number of cases submitted | Percentage of reports fit for purpose at the point of submission (Target 75%) | Total number of cases assessed by Executive | Total number of cases referred to a panel of Authority Members |
|--------------|---------------------------------|---|---|--|
| January | 84 | 79% | 80 | 4 |
| February | 98 | 84% | 89 | 9 |
| March | 113 | 84% | 92 | 21 |
| April | 85 | 92% | 75 | 10 |
| May | 100 | 89% | 97 | 3 |
| June | 108 | 95% | 99 | 9 |
| Total | 588 | 87% | 532 | 56 |

Profile of panel cases

| | Total number of cases referred to a panel of Authority Members | Non-directed altruistic | Paired /Pooled | Adult-to-adult liver |
|--------------|--|-------------------------|----------------|----------------------|
| January | 4 | 3 | - | 1 |
| February | 9 | 3 | 6 | |
| March | 21 | 5 | 14 | 2 |
| April | 10 | 4 | 6 | - |
| May | 3 | 3 | - | - |
| June | 9 | 2 | 6 | 1 |
| Total | 56 | 20 | 32 | 4 |

Turnaround times in days

| | Total number of cases assessed by Executive | Turnaround time (working days) | Total number of cases referred to a panel of Authority Members | Turnaround time (working days) |
|---------------|---|--------------------------------|--|--------------------------------|
| Target | | 5 | | 10 |
| January | 80 | 0.7 | 4 | 3.2 |
| February | 89 | 0.9 | 9 | 3.7 |
| March | 92 | 1.6 | 21 | 2.3 |
| April | 75 | 0.9 | 10 | 2.5 |
| May | 97 | 1.8 | 3 | 2.5 |
| June | 99 | 1.2 | 9 | 4.9 |

Points to note

6. We are pleased to see that a significant proportion of IA reports received during this six month period met the standard required on submission.
7. Two reports, which both related to one case (one was a follow-up report), were turned down during the reporting period.
8. One altruistic case remains outstanding with additional information having been sought from the relevant Unit.
9. Following on from the completion of the reaccreditation process in March most IAs were successfully reaccredited. Of the 134 IAs that required assessment against the published criteria:
 - 102 were automatically reaccredited as they had met both the quantity and quality targets;
 - 32 required refresher training, of these 22 passed;
 - Seven have since stepped down from the role due to retirement or a change in circumstances; and
 - Three did not reach the required standard.

10. The Executive recommended appropriate steps to be taken in each case where the IA had not met the minimum standards to the Transplantation Working Group (TWG). The Group accepted the Executive's recommendation to pass one IA due to extenuating circumstances. The second attended the IA training day on 30 June to refresh her skills and has now been recredited, and the third intends to come to the next training day.

11. Twenty one people have been trained as IAs since March 2011 across the 24 transplant centres.



Authority paper

| | | | |
|--------------------|--------------|------------------------|-------------|
| Date | 26 July 2011 | Paper reference | HTA (39/11) |
| Agenda item | 11 | Author | Sue Martin |

Financial report at end June 2011

Introduction

1. This paper provides a report of the HTA's financial position as at 30 June 2011. This is the first full report of the new business year, after the first three months.
2. The report provides commentary on the following areas:
 - budget developments
 - overview of financial position to 30 June 2011
 - income and expenditure variances
 - forecast outturn
 - other key performance indicators
 - financial risks

Budget developments

3. The Department of Health (DH) has now confirmed Capital Grant-in-aid (GIA) funding for 2011/12 of up to £75k. This is the amount we estimated as necessary for IT development to support the Organ Donation Directive. We will draw the funding down later in the year when the development commences.

Overview of financial position at 30 June 2011

4. **Annex A** shows the summarised financial position for the year to 30 June 2011. At that date, there was an overall under-spend on revenue expenditure of **£146k** and **£124k** more income in total than anticipated. Together these resulted in **£270k** more surplus than expected.

Income – variances to 30 June 2011

5. **Annex B** provides a more detailed breakdown of income generated to 30 June 2011. In the three months, compared to budget, there is more income than expected. The April invoices for human application licences were **£119k** more than expected, due to the profile of establishments being more complex than our conservative estimates. In addition, invoices have been issued to establishments requiring new licences within the post mortem and research sectors for **£4.2k** and **£1.2k** respectively.
6. The first revenue GIA drawdown was requested in early June. Due to changes in their process, DH were unable to transfer funds in June and we expect to receive the money in July.

Expenditure – variances to 30 June 2011

7. **Annex C** shows expenditure as at 30 June 2011 for staff and non-staff costs. To date, there is an overall under-spend of **£146k**.
8. The under-spend on staff costs of **£84k** is the result of unfilled posts. Added to this is a net under-spend on non-staff costs of **£62k**. At this point in the year, there has been less spend on training and recruitment and IT development than expected and capital charges have differed from our assumptions.
9. The details of variances are summarised below:

| Expenditure Variances | | |
|------------------------------|---------------|---|
| | £ | Notes |
| Staff costs | 83,769 | Vacant posts which are under review. |
| Non staff costs | 62,510 | This variance is analysed in greater detail in the lines below. |
| Training & Recruitment | 15,180 | Activity has not happened as early in the year as expected. |
| IT & Telecommunications | 15,811 | IT development has not happened as early as expected. |
| Legal | (11,025) | Additional cost because of advice required, primarily for the Employment Tribunal. |
| Capital charges | 26,975 | Changes to assumptions relating to depreciation of the refurbishment costs for the new office. This was allocated from DH after the budget was set. |
| Other variances | 15,569 | The part of accommodation costs based on usage has been a little less than expected and the staff survey is to take place later in the year. |

1 () denotes an over-spend

10. **Annex D** provides an analysis of expenditure by Directorate. All Directorates are under-spending for the reasons above. The small overspend by the HTA Board at this stage in the year is due to travel and subsistence claims being higher than expected.

Forecast outturn

11. At this three month stage, staffing and spend plans have been reviewed with Directors for an initial review of likely forecast outturn. There are uncertainties until our plans are further advanced, but it is clear that we will spend significantly less on staff costs than budgeted. In addition, the report shows that we expect to spend less in the year on capital charges (for the reasons above), consultancy (the staff survey has been sourced more cheaply than expected) and conference attendance. The other small differences between budget and forecast are not significant. The pressures on our legal budget may continue and we will estimate any overspend later in the year.

12. The forecast outturn at this stage is at least **£278k** less expenditure than expected, and this is likely to increase later in the year. We already have **£124k** more income than expected so we report a forecast surplus of **£402k** 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

13. Total reserves at the end of June are £3.7m and our cash balance is £2.9m.

Debtors

14. As at 30 June our licence fee gross debtor balance was **£219k**. This includes debts being settled from last year, debts relating to the invoice run made in April and those from invoices issued in May and June for new licences. Fees are outstanding from a total of 22 establishments. **43%** is due from NHS bodies, **29%** from private sector bodies and **28%** due from other non-NHS bodies.

15. There are 8 establishments who have not paid April invoices (of **£90k**) and are causing us concern. These are being reviewed for legal action.

Prompt payment

16. For the three months ended 30 June, 76% of invoices were paid within 5 days and 98% within 10 days. Average payment time was 3.2 days.

Financial risks

17. 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.

| 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. |
| Establishments change their profile resulting in a reduction in hubs and satellites, and licensed activities, leading to a reduction in fee income. | Insufficient financial resources Failure to manage change | HTA undertake a periodic review of establishments and expected income. Budgets would then need to be managed to reflect income or unavoidable costs recovered through licence fees. |
| 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. |

Conclusion

18. The Authority is asked to note the financial position as at 30 June 2011.

Human Tissue Authority

Summary - Income & Expenditure

Annex A

For the Three Months Ending 30 June 2011

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

| INCOME & EXPENDITURE SUMMARY | | | | | | | |
|---|------------------|------------------|------------------|------------------|-----------------|------------------|--------|
| Income | (1,524,492) | (1,400,250) | (124,242) | (5,207,242) | (5,083,000) | (124,242) | 2.44% |
| Less: | | | | | | | |
| Expenditure | 1,103,929 | 1,250,208 | (146,279) | 4,759,998 | 5,037,952 | (277,954) | -5.52% |
| Gross (surplus)/deficit of income over expenditure | (420,563) | (150,042) | (270,521) | (447,245) | (45,048) | (402,197) | |
| Net (surplus)/deficit of income over expenditure | (420,563) | (150,042) | (270,521) | (447,245) | (45,048) | (402,197) | |

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Human Tissue Authority

Member Income Summary

Annex B

For the Three Months Ending 30 June 2011

| | Year to Date | | | FORECAST | | | |
|---|------------------|------------------|----------------|------------------|------------------|----------------|---------------|
| | Actuals £ | Budget £ | Variance £ | Outturn £ | Budget £ | Variance £ | % |
| Grant In Aid | | | | | | | |
| GIA | 0 | 0 | 0 | 954,000 | 954,000 | 0 | 0.00% |
| Sub-Total | 0 | 0 | 0 | 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 | 1,597,200 | 1,596,000 | 1,200 | 0.08% |
| Public Display | 0 | 0 | 0 | 19,000 | 19,000 | 0 | 0.00% |
| Research | 4,200 | 0 | 4,200 | 676,200 | 672,000 | 4,200 | 0.63% |
| Human application | 1,418,871 | 1,300,000 | 118,871 | 1,718,871 | 1,600,000 | 118,871 | 7.43% |
| Sub-Total | 1,424,271 | 1,300,000 | 124,271 | 4,152,271 | 4,028,000 | 124,271 | 3.09% |
| 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 | 1,524,492 | 1,400,250 | 124,242 | 5,207,242 | 5,083,000 | 124,242 | 2.44% |

Human Tissue Authority

Summary - Expenditure

Annex C

For the Three Months Ending 30 June 2011

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

| EXPENDITURE SUMMARY | | | | | | | |
|---|------------------|------------------|------------------|------------------|------------------|------------------|---------------|
| Staff Costs | 666,235 | 750,004 | (83,769) | 2,745,807 | 3,000,017 | (254,210) | -8.47% |
| Non Staff Costs | 437,694 | 500,204 | (62,510) | 2,014,191 | 2,037,935 | (23,745) | -1.17% |
| Gross Costs before Exceptional Items | 1,103,929 | 1,250,208 | (146,279) | 4,759,998 | 5,037,952 | (277,954) | -5.52% |
| Exceptional items | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| Total Expenditure | 1,103,929 | 1,250,208 | (146,279) | 4,759,998 | 5,037,952 | (277,954) | -5.52% |
| | ===== | ===== | ===== | ===== | ===== | ===== | ===== |

Human Tissue Authority

Directorate Summary

Annex D

For the Three Months Ending 30 June 2011

| | Year to Date | | | | FORECAST | | | |
|---|------------------|------------------|------------------|----------------|------------------|------------------|------------------|---------------|
| | Actuals £ | Budget £ | Variance £ | % | Outturn £ | Budget £ | Variance £ | % |
| Communications and Public Affairs | 59,389 | 67,544 | (8,155) | -12.07% | 285,013 | 258,296 | 26,717 | 10.34% |
| Regulation | 359,849 | 407,671 | (47,822) | -11.73% | 1,446,334 | 1,661,684 | (215,350) | -12.96% |
| Strategy and Quality | 57,965 | 73,068 | (15,102) | -20.67% | 282,267 | 298,270 | (16,003) | -5.37% |
| HTA Board | 40,648 | 38,715 | 1,933 | 4.99% | 163,318 | 162,859 | 459 | 0.28% |
| Resources | 451,002 | 506,745 | (55,743) | -11.00% | 1,974,033 | 2,028,979 | (54,946) | -2.71% |
| Chief Executive's Office | 135,077 | 156,466 | (21,389) | -13.67% | 609,032 | 627,864 | (18,832) | -3.00% |
| Subtotal | 1,103,929 | 1,250,208 | (146,279) | -11.70% | 4,759,998 | 5,037,952 | (277,954) | -5.52% |
| Total Directorate(s) Expenditure | 1,103,929 | 1,250,208 | (146,279) | -11.70% | 4,759,998 | 5,037,952 | (277,954) | -5.52% |

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Authority paper

| | | | |
|--------------------|--------------|------------------------|-------------|
| Date | 26 July 2011 | Paper reference | HTA (40/10) |
| Agenda item | 12 | Author | Sue Martin |

Report from the Audit Committee 2 June 2011

Purpose of paper

1. This paper highlights the key points discussed at the Audit Committee on 2 June and presents the Committee's annual report to the Authority. The minutes of the meeting are at Annex A. The annual report is at Annex B.

Recommendations

2. That Authority Members note the points and the report.

Key Points

3. **Annual report and accounts** – The Committee reviewed the draft reports and accounts and recommended that they are signed by the Chief Executive. The reports are informed by the internal audit annual report and the report on information risks. The National Audit Office (NAO) reported their satisfaction with the accounts and made no recommendations.
4. **Internal audit** – The year end annual report and two final audit reports were reviewed by the Committee. RSM Tenon assessed the Human Tissue Authority systems as green or green/amber. Good progress had been made on previous recommendations, although some are outstanding due to remaining Customer Relationship Management (CRM) system implementation (expected in the next few months). The contract with RSM Tenon has now ended and Grant Thornton will provide internal audit services in future. The Committee approved Grant Thornton's suggested plan for internal audit for 2011/12.

5. **Information Risk** – The annual report confirmed that the HTA is largely compliant with Cabinet Office requirements. The Committee asked for deadlines to be put on the areas for attention and noted that these areas do not compromise the HTA as there is a good security culture.
6. **Risk Management** – The Committee approved an updated strategy that now includes details of how assurance is provided that risks are being controlled effectively. The strategic risk register reported that the level of strategic risk faced by the HTA was unchanged, with failure to manage change still being the most significant (amber) risk. Since the meeting the risk of inability to carry out statutory remit has also been assessed as amber due to regulation staff resignations.
7. Allan Marriott-Smith explained the risks faced in his Strategy and Quality Directorate and how they are being managed. The key risk areas are: availability of staff to approve transplants; possible gaps in policies covering all legal issues; and the need to establish how the Authority's role in approving transplants will be met when the HTA's functions transfer.



Minutes of Audit Committee

Date 2 June 2011
Venue Human Tissue Authority
151 Buckingham Palace Road
London, SW1W 9SZ

Present

Members

Professor Michael Banner (Chair)
Ms Pamela Goldberg
Mr Brian Coulter
Professor Susan Dilly

In attendance

Ms Sue Martin (Director of Resources)
Mr Craig Muir (Chief Executive)
Baroness Diana Warwick (Chair of the HTA)
Ms Morounke Akingbola (Head of Finance)
Miss Nicola Harlow (Finance Manager)
Mr Allan Marriott-Smith (Director of Strategy & Quality)
Mr Patrick Irwin (Department of Health)

National Audit Office

Paul Holland
Dean Parker

Internal Auditors

Stuart Hopkinson (RSM Tenon)
Omer Tauqir (Grant Thornton)
Caroline Ross (Grant Thornton)

Item 1 – Welcome and Apologies

1. Apologies were received from Ms Suzanne McCarthy.
2. The Chair welcomed Omer and Caroline from Grant Thornton to the meeting.

Item 2 – Declarations of Interest

3. None declared.

Item 3 – Minutes from 11 February 2011 (AUD 35-11)

4. Minutes were agreed.

Item 4 – Matters Arising

5. Sue Martin provided progress on actions from the February Meeting:

- Page 3
 - The Financial Procedures Manual and Procurement Policy wording has been amended as recommended by the Committee.
- Page 5
 - Sue Martin had reported to the Authority recently on the position with shared services. The key points are:
 - HR shared services are not being progressed at present. The emphasis is on ALBs working together with some taking the lead on particular HR topics. The HTA will continue to work closely with CQC and HFEA.
 - The business case for finance shared services is due to be submitted to the DH transformation board imminently. The CQC are scheduled to move transactions to shared services in October 2011. The impact and time scale for the HTA is uncertain as yet.
 - Legal shared services work is focussing on using government lawyers.
 - The HTA has already moved to 151BPR and therefore has no further action to take on estates.
 - Procurement developments are likely to mean more use of central government contracts.
 - It is acknowledged that communications are sovereign to the organisation. There may be opportunities to share aspects (such as the press cutting service that the HTA already shared with CQC).

Item 5 – Internal Audit

6. Stuart Hopkinson presented the Data Security Report and the Follow Up Report to the Committee, highlighting the amber/green ratings. He informed the Committee that of the follow up recommendations 50% had been implemented and the remaining 50% were in progress and on-going.
7. In the annual report, overall governance has been awarded a green status showing that the HTA's governance is of a high standard and that recommendations have been taken forward and actioned where necessary. Risk management was rated amber and control green.

8. Susan Dilly questioned the rating of two areas in Annex A of the annual report. Targets were not met in Inspection and Licensing and in Core Financial Controls purchase orders were not always being raised before ordering. Both these audit areas had been assessed as amber/green. Stuart Hopkinson explained that although these two areas are highlighted in the findings of the report, they are not significant enough to reduce the overall governance. Susan asked if the 7 day target for making risk assessments was appropriate and what the position was now.

ACTION 1 – Sue Martin to establish the present target and performance for making risk assessments.

9. Omer Tauqir asked whether the amber rating for risk management applied as at the time of assessment or as at the year end and Stuart confirmed that it applied to the assessment at the time of the audit work.
10. Michael Banner thanked RSM Tenon on behalf of Audit Committee for the internal audit work. Stuart Hopkinson left the meeting.

Item 6 – Audit Tracker Report

11. The Committee were invited to comment on the audit tracker.
12. Brian Coulter noted the delay in implementing some recommendations because of the need for IT developments. Sue explained that development on CRM licensing continues from 6 June. She confirmed that transition issues had been considered but that integration with CQC systems is not straightforward as CQC use a different CRM system.

Item 7 – Information Risk Management

13. Sue Martin presented the SIRO report and highlighted that the HTA is largely compliant with Cabinet Office requirements. There are two key areas for attention: Government protective markings are not always used in the HTA; and more needs to be recorded regarding information assets. However this does not result in information being mistreated as the HTA has a good security culture.
14. The Committee asked for time-scales to be set for the completion of required actions.

ACTION 2 - Sue Martin to add time-scales to the actions required in the Security Risk Management Overview.

Item 8 – Audit Committee Report

15. Michael Banner presented the Audit Committee Report and the Committee confirmed that it summarised their work effectively.
16. Paul Holland asked that paragraph 20 be amended as most IFRS were implemented in the previous year.
17. Brian Coulter requested that paragraph 25 be expanded to describe the current challenges regarding transition and the role of the Committee to support effective ongoing business.

ACTION 3 – Sue Martin to amend the Report of the Audit Committee at paragraph 20 and 25 and submit to Committee for final sign off.

Item 9 – Annual Report and Accounts

18. Morounke Akingbola presented the Annual Accounts and invited the Committee to raise any points and then recommend that they are signed by the Chief Executive.
19. A few amendments to wording were requested and the report and accounts were endorsed.

ACTION 4 – Morounke Akingbola to amend the wording in the Annual Report and Accounts as suggested by the Audit Committee.

Item 10 – External Audit – NAO

20. Paul Holland reported to the Committee that NAO's Audit Completion Report makes no recommendations and that the financial statements should be certified with an unqualified audit opinion. The adjustments listed are not systematic errors and are not material to the accounts.
21. The issue of 'going concern' was considered. This may become an issue in the future, closer to transition, but is not for this year's annual accounts.
22. Susan Dilly asked about the statement in paragraph 3 of the report that the report must not be shared without the written consent of the NAO. Dean Parker confirmed that this is standard wording but that the HTA may put the report on their website.

Item 11 – Risk Update

23. Sue Martin presented the updated Risk Management Strategy that included information about assurances. The Committee suggested that the work of the Audit Committee and any learning from complaints may be sources of assurance. The Committee approved the updated strategy.
24. The Committee reviewed the latest risk register. Sue confirmed that there were no changes in risk levels. It was suggested that the register might be developed to identify the movement of risk levels, causes of risks outside the HTA's control, greater clarity of actions that are outstanding and to move key sources of assurance to clarify that these are provide assurance about the level of residual risk.
25. Grant Thornton offered to provide examples of other risk registers

ACTION 5 – Sue Martin to review the format of the Risk Register and to report back to the Audit Committee.

26. Allan Marriott-Smith, Director of Strategy & Quality, joined the meeting to discuss the risks in his Directorate. Allan outlined four areas of risk:
 - Operational risk, relating to resourcing - the Transplants team deal with up to 100 cases per month and cover for staff absences can be difficult. Other members of HTA staff assist and more are being trained in transplant approvals to reduce this area of risk. Two staff in the team are classed as front-line so recruitment can be swift if necessary.
 - Legal/policy risk - a review is being undertaken to highlight any gaps in requirements, that will then be targeted for action and reported to the Authority.
 - Capacity to deliver the business plan in changing circumstances – this is reviewed regularly and reported to the Authority.
 - Governance risks in transition – the role of the Authority in approving transplants and arrangements when the HTA functions move to CQC will need to be established.

Item 12 Internal Audit

27. Omer took the Committee through the Internal Audit Plan for 2011/12 that Grant Thornton have developed following meetings with SMT and the Chair of the Audit Committee. Omer confirmed that Grant Thornton would wish to meet with NAO to agree timing of the related audits.
28. It was suggested that the major incident reporting audit may be more pressing than other audits that are currently planned earlier in the year and Omer agreed

to propose appropriate timing for all the audits. The Committee approved the plan.

Item 13 - AOB

29. Sue Martin reported that there had been no identified cases of fraud or suspected fraud.
30. The Chair, on behalf of the Committee, noted that this was Brian Coulter's last meeting as an Audit committee member and thanked Brian for his helpful and robust contributions to the Committee.

The meeting closed at 12:45



Report of the Audit Committee 2010/11

1. This report summarises the Committee's work during the year and gives my opinion on the Human Tissue Authority's risk management and internal control arrangements. The report forms part of the assurance processes, which support the Accounting Officer's Statement on Internal Control (SIC).

Membership

2. Membership of the Audit Committee throughout the year has been:
 - Michael Banner, Authority member (Chairman)
 - Brian Coulter, Authority member
 - Pamela Goldberg, Authority memberAnd from the September meeting:
 - Suzanne McCarthy, Authority member
 - Susan Dilly, Authority member
3. There are regular attendees from the executive, RSM Tenon (the HTA's internal auditors), the National Audit Office and the Department of Health. The Authority met in normal session four times in the year (May 2010, September 2010, November 2010 and February 2011).

Role and function

4. Our formal role is to advise the Accounting Officer and Authority on:
 - the strategic processes for risk, control and governance and the Statement of Internal Control
 - the accounting policies, the accounts, and the annual reports of the HTA, including the process for review of the accounts prior to submission for audit, levels of error identified, and management's letter of representation to external auditors
 - the planned activity and results of both internal and external audit;
 - adequacy of management response to issues identified by audit activity, including external audit's management letter
 - assurance relating to corporate governance requirements for the HTA

- (where appropriate) proposals for tendering for either Internal or External Audit services or for purchase of non-audit services from contractors who provide audit services
 - anti-fraud policies, whistle-blowing processes, and arrangements for special investigations.
5. There is an annual cycle of matters to consider, with our regular business focussing on assurance and risk management processes, as well as matters arising from internal and external audit work. At each meeting, we received progress reports on all these areas.

Review of Committee effectiveness

6. The Committee reviewed its effectiveness in November 2010, using the NAO assessment checklist. It concluded that the Committee supports the Authority effectively and that the actions taken in response to the 2009 review had all been implemented. No further actions are necessary at this time.

Risk Management

7. The Committee has reviewed developments in the HTA's risk management processes throughout the year. In September 2010, the executive and the Authority considered afresh strategic risks, alongside the consideration of future strategic objectives. Directors have attended the Audit Committee on rotation to discuss the risks they own and areas of risk within their Directors.
8. Internal Audit has conducted a Risk Management – Assurance Stocktake which concludes that the HTA has developed a more robust risk management framework over the last year that has enabled risk management to become more embedded in the organisation. Internal Audit made further recommendations about assurance mapping and reporting that are in the process of being implemented.
9. The success of risk management continues to rely on staff at all levels ensuring there is effective management of risks. This requires the ongoing commitment and support of Directors and managers in encouraging the further development of risk management culture.

Information and Data Security

10. The emphasis on the protection of information and data across Whitehall continues and the guidance and requirements with which the HTA is required to comply have been updated in the year.

11. The Cabinet Office publishes the HMG Security Policy Framework (SPF) and Information Assurance Standards. These outline the mandatory security requirements and management arrangements to which all departments and arms length bodies must adhere.
12. Management Boards are required to include a Senior Information Risk Owner (SIRO). Within the HTA, the Director of Resources fulfils this role.
13. The SIRO is obliged to provide an assessment of information risk management to the Accounting Officer annually. This report from the SIRO will underpin what is included within the HTA's Statement on Internal Control (SIC) and is also a key reporting tool for the Department of Health (DH) and the Cabinet Office. The HTA has reported on the mandatory requirements of the SPF to DH in the Security Risk Management Overview (SRMO).
14. The Committee has agreed the SIROs report for 2010/11. This report states that the HTA has applied the requirements in a form that is proportionate with HTA work and risk. No significant data losses have been identified and the SIRO considers that information risk is being managed adequately. For the relevant requirements in the SRMO, there are no areas of non-compliance that put information security at risk. The HTA intends to continue to develop its information asset register and promote the use of protective markings amongst staff as required.
15. Internal Audit also undertook an audit in September 2010 on Data Security and Information Governance. The conclusion was that there is Amber/Green assurance that key controls are in place regarding the HTA's information governance framework. Internal Audit suggested further attention is given to controls over removable media and this has been addressed.

Internal Audit

16. Internal Audit for 2010/11 was provided through a contract agreement with RSM Tenon. The Committee endorsed the Internal Audit strategy and plans for the year, and monitored work progress.
17. Management has responded positively to audit findings and recommendations and has taken, or is in the process of taking, action to implement agreed recommendations from Internal Audit Reports. Of 25 recommendations made during the year, 16 have been fully completed and 9 are in progress.
18. In his annual report, the Head of Internal Audit gave internal audit's opinion ss:

- Green for the governance framework
- Amber for risk management, with the HTA being defined as a risk defined organisation
- green for control

19. From 2011/12, the HTA's internal auditors will be Grant Thornton, who work in partnership with the Department of Health, and the HTA will take up this shared service. Resources are considered sufficient to deliver the 2011/12 programme of work.

External Audit

20. NAO officials attend all Committee meetings and continue to make a valuable contribution to our discussions. The NAO has continued to support the HTA in implementing the International Financial Reporting Standards and conducted audits at the appropriate trigger points. Management have put the recommendations and advice from these, and the interim audit, into practice. The NAO have given an unqualified opinion on the 2010/11 accounts and have agreed the Statement on Internal Control.

Assurance processes

21. The Chief Executive meets Directors at least monthly individually to review the delivery of their responsibilities. Directors hold similar meetings with their staff and ensure that controls are in place on an ongoing basis. The Senior Management Team of the Chief Executive and Directors meet at least monthly and approve policies, review exceptions and identify and act on lessons learned.

22. The Internal Audit Risk Management – Assurance Stocktake recognises the assurance provided by managers, recommending that these are documented. More formal processes are being introduced, in a proportionate way for the type of organisation the HTA is.

23. I believe that ongoing management review and communication, supported by the findings of audits and DH gives sufficient evidence to provide the Chief Executive with comfort that the systems are sufficiently robust, and that the exceptions are relatively immaterial.

Statement on Internal Control

24. The Statement on Internal Control (SIC) is a key part of the Annual Report and Accounts. It is signed by the Chief Executive and explains how governance responsibilities have been discharged. This report shows the how risk

management processes within the HTA have become embedded. I consider that there is sufficient evidence of effective governance processes to support the signing of the SIC. There are no material issues to be brought to the attention of the Accounting Officer.

Summary

25. This has been a year of consolidation and further development in governance within the HTA. The Committee has been kept aware of the current challenges regarding transition arising from the Arms Length Bodies review and will continue to support the executive to ensure effective ongoing business. I am satisfied with the arrangements for risk management and the assurance processes.

Michael Banner
Chairman, Audit Committee

May 2011

Authority paper

| | | | |
|--------------------|--------------|------------------------|----------------------|
| Date | 26 July 2011 | Paper reference | HTA (41/11) |
| Agenda item | 13 | Author | Allan Marriott Smith |

Strategic Performance Review – June 2011

Purpose of paper

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

Background

2. The Authority has agreed to monitor a set of KPIs that demonstrate whether the Human Tissue Authority's (HTA) strategic aims are being delivered. This report presents results at the end of the first quarter.

Progress in June 2011

Regulation

3. Over the last few months there have been a number of changes to inspection processes and timelines. The transition to the new procedures has resulted in targets for issuing draft reports (**KPI 1.5**) and managing Corrective and Preventive Action (CAPA) plans (**KPI 1.7, KPI 1.13**) being missed across all sectors. However, the business plan indicates an overall improvement in June against these targets in comparison to May.
4. A streamlined process for monitoring CAPAs has been developed which should significantly improve the efficiency of the process and result in an improvement in meeting CAPA targets. In addition, Regulation Managers will take a more active role in assisting Designated Individuals determine appropriate and realistic target dates for completion of individual actions.

Strategy and Quality

5. All KPIs are on target.
6. With the resource currently available all KPIs are achievable by the stipulated deadlines. The only potential exceptions to this are **KPIs 1.14** and **1.15** which are contingent on agreement to the proposed approach being reached at the July Authority meeting.

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 2% against a target rate of 5%. This rate has been calculated by taking the complement of staff that has been agreed by the Senior Management Team as of the end of June (48) and the number of vacancies which are still in the process of being recruited (1 Regulation Manager post). The Regulation Directorate is currently undertaking an exercise to identify the steady state target level for staffing, and the complement may change as a result of this.
10. **KPI 3.2** relating to attrition is judged amber. During June two staff members joined the HTA (Sara-Jane Wakefield and Allison Cummings) and one staff member left (Teena Chowdhury). Three further Regulation Managers and the Quality and Policy Manager will leave the HTA between July and September.



Authority paper

| | | | |
|--------------------|--------------|------------------------|-------------------------|
| Date | 26 July 2011 | Paper reference | HTA (42/11) |
| Agenda item | 14 | Author | Ariel Armarego-Marriott |

Enquiries report

Purpose of paper

1. This paper accompanies the quarterly enquiries report for quarter one (Q1; April–June) of the 2011/2012 financial year (Appendix A); and for the whole of the 2010/2011 financial year (Appendix B). It provides a report on how we are meeting targets and an overview of the type and number of enquiries received.

Key observations

2. In 2010/11, the target was for 95% of enquiries to be responded to *within 20* working days. For the 2011/2012 financial year we are working towards a target of responding to 95% of all enquiries *within 10* working days: (this is a Key Performance Indicator for enquiries from licenced establishments). Freedom of Information (FOI) enquiries will, as of 1 July, have a target of being responded to in an *average* of 10 days (there is a legal requirement to respond within 20 days).
3. We are pleased to note that the average time to respond to enquiries in Q1 of 2011/12 was 4.7 working days. This compares with 7.3 days in the equivalent quarter of 2010/11, and 7.7 days for the whole of 2010/11.
4. In this report, the response times are reported against the previous target of 20 working days. Because of technical difficulties, we have not reported on the new 10 day targets, but aim to do so in the next report. In Q1 of 2011/12, 97% of enquiries were responded to within 20 working days, compared with 94% for the equivalent quarter of 2010/11, and 94.4% for the whole of 2010/11. This is illustrated in Table four
5. Some key observations from 2011/12:

- a) The total number of enquiries for Q1 of 2011/12 has reduced considerably compared with the number of enquiries from the corresponding quarter of 2010/11, though it is relatively consistent with the number of enquiries from quarter three (Q3) and quarter four (Q4) from 2010/11.
- b) As in previous reports, we received more enquiries by phone than any other channel.

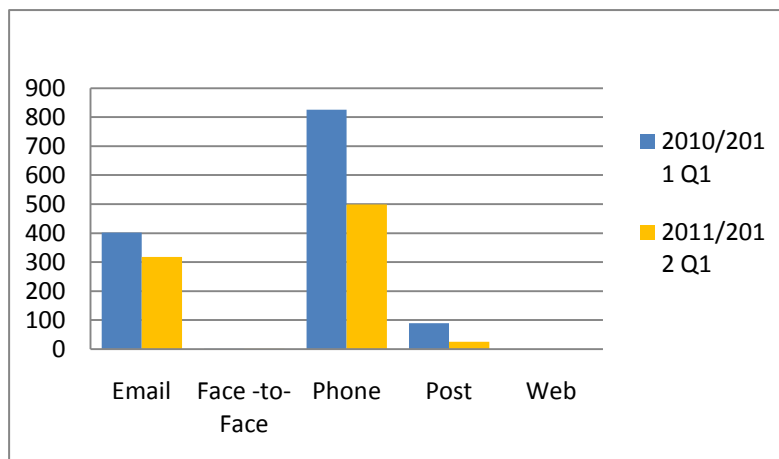


Table 1: Enquiries channels: Quarter one

- c) There was a decrease in the number of postal enquiries Q1 2011/12 compared with the equivalent quarter of 2010/11. These were mostly on body donation.
- d) As usual, in Q1 2011/12 we received more body donation enquiries than on any other subject. Whilst this marked a strong decline when compared against the equivalent quarter last year, this was only a slight decrease compared with Q4 of 2010/11. These differences may be due to improvements made to our body donation web pages in January 2011.
- e) The General Directions resulted in 19 enquiries throughout May and June, some of which requested clarity on a few of the questions, while others related to the submission of the self-assessment forms.
- f) May saw a high number of FOI requests with seven for the month, compared to the more usual number of up to three. These covered the usual range of topics and were not the result of any specific incident. Only one related to the Arms Length Bodies review and the future of the HTA.
- g) There was a significant decrease in the number of enquiries relating to the disposal of human tissue. This quarter saw only seven, compared

with 20 from the same quarter last year. Again this figure is on par with the number of disposal-related enquiries in Q4 of 2010/11.

- h) In comparison with the data from the last financial year, Q1 saw a 50% drop in the number of enquiries from the tissue and cells for treatment (human application) sector. The Post Mortem and Anatomy sectors experienced almost twice as many enquiries during Q1 as is usual. Most enquiries were received during May and June and appear to be due to the recent self assessment requested of all licenced establishments in these sectors.

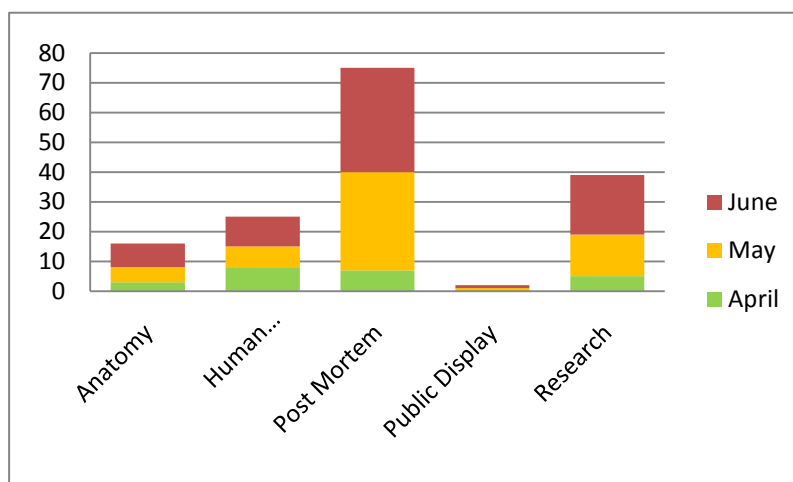


Table 2: Enquiries per sector: Q1 11/12

- i) In May and June, 100% of enquires were answered in less than 20 days, with the average for Q1 being 97% (in April the figure was 91%). This is comparable to Q4 2010/11 which saw 97.3% of enquiries answered in 20 days. This is still above the target level of 95%; and we are working towards reducing the response time to 10 working days.
- j) The two complaints referenced in the table in Annex A were not complaints s defined by our complaints policy.

6. Some key observations from the 2010/2011 financial year:

- a) Q3 and Q4 saw a decrease in the overall number of enquiries, with the numbers falling below 1000.
- b) There was a significant decrease in the number of postal enquiries in Q4 to 38. This was down on the 53 recieved in Q3; itself low compared with 89 and 68 received in Q1 and quarter two (Q2), respectively.

- c) Though we received more enquiries by phone than by any other medium, there was a decrease in the number of phone enquiries over Q3 and Q4. This decline was mirrored in the number of body donation enquiries.

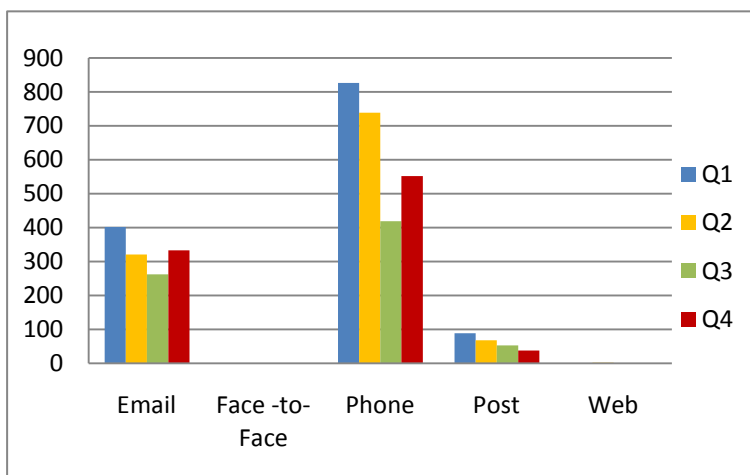


Table 3: Enquiries Channel 2010/2011

- d) Over the whole of the financial year, 94.4% of enquiries were responded to within 20 working days. This number is improving, with Q4 recording 97.3% of enquiries answered within this time-frame.

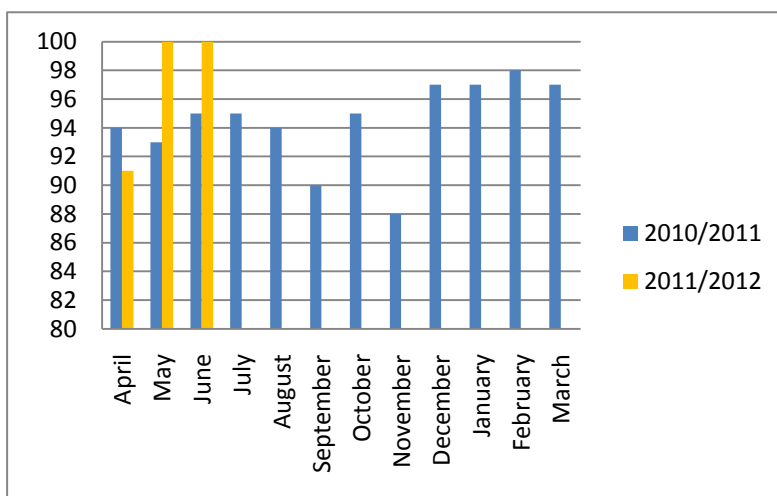


Table 4: Percentage of enquiries answered within 20 working days

- e) Q4 saw a 10-fold increase in the number of FOI requests, with 23 requests compared with the two or three usual for each quarter. This was partly a result of the list of licensed establishments not being unavailable on the website at the time. As a result, 74% of the financial year’s FOI requests were dealt with in Q4.

- f) The average response time for all enquiries was 7.7 days, though this time has been steadily decreasing from Q2, and continued to decrease into the Q1 of 2011/12.
- g) There was a 3-fold increase in the number of communications-related enquiries in Q3. These primarily related to subscriptions to our newsletter, feedback on the website and requests from the media.
- h) Enquiries relating to consent rose in the Q3 too, with 21 enquiries against the more common level of 13–15 per quarter.
- i) There was a more than 50% drop in the number of organ transplant enquiries during Q3.
- j) Q4 also saw a marked increase in the number of IT enquiries, totalling almost 60% of such enquiries for the entire financial year.
- k) Body donation enquiries experienced a sharp drop in number between Q2 and Q3, and have fluctuated only slightly since then. We are uncertain what caused this decrease however we are updating to all Human Tissue Authority (HTA) body donation pages so that they appear in any relevant google searches.

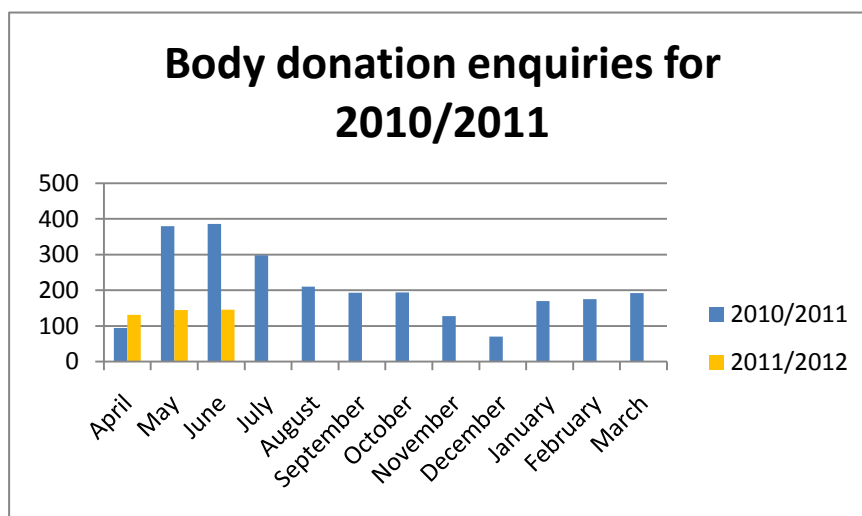


Table 5: Body Donation Enquiries for 2010/2011

- l) Over the year we have seen the number of recorded enquiries fall. This may be related to our Customer Relationship Management (CRM) system which was launched in March 2010. This system is currently being updated to improve usability, with the aim that all interactions will be recorded through CRM.

Annex A

HTA quarterly enquiries report April 2011 – June 2011

Overview of enquiries by month

| | Month | | | Quarter |
|------------------------|------------|----------|-----------|---------|
| | April 2011 | May 2011 | June 2011 | Q1 |
| | | | | |
| Total | 220 | 293 | 330 | 843 |
| Media | 5 | 7 | 7 | 19 |
| Professional | 66 | 128 | 164 | 358 |
| Public | 60 | 93 | 82 | 235 |
| Channel | | | | |
| Email | 83 | 107 | 128 | 318 |
| Face -to-Face | 0 | 1 | 0 | 1 |
| Phone | 137 | 167 | 195 | 499 |
| Post | 0 | 18 | 7 | 25 |
| Web | 0 | 0 | 0 | 0 |
| Subject | | | | |
| Anatomy | 3 | 5 | 8 | 16 |
| Body Donation | 131 | 145 | 146 | 422 |
| Bone Marrow Donation | 1 | 0 | 0 | 1 |
| Business and Strategy | 0 | 0 | 0 | 0 |
| Communications | 1 | 2 | 3 | 6 |
| Complaints | 1 | 0 | 1 | 2 |
| Consent | 7 | 2 | 6 | 15 |
| Directions | 0 | 5 | 14 | 19 |
| Disposal | 1 | 4 | 2 | 7 |
| DNA | 1 | 1 | 1 | 3 |
| Enquiries | 0 | 0 | 0 | 0 |
| Ethics | 1 | 0 | 2 | 3 |
| Fees | 0 | 1 | 0 | 1 |
| Finance | 1 | 2 | 0 | 3 |
| Freedom of Information | 3 | 7 | 1 | 11 |
| Governance | 0 | 1 | 0 | 1 |
| HR | 0 | 0 | 1 | 1 |
| Human Application | 8 | 7 | 10 | 25 |
| Import and Export | 3 | 2 | 7 | 12 |
| Inspections | 1 | 0 | 0 | 1 |
| IT | 5 | 1 | 3 | 9 |

| | | | | |
|---|-----|------|------|------|
| Knowledge and Quality Management | 1 | 1 | 0 | 2 |
| Legal Advice | 0 | 0 | 0 | 0 |
| Legislation | 4 | 1 | 4 | 9 |
| Licensing | 21 | 36 | 46 | 103 |
| Organ Transplants | 9 | 11 | 4 | 24 |
| Parliamentary Questions | 0 | 0 | 0 | 0 |
| Post Mortem | 7 | 33 | 35 | 75 |
| Public Display | 0 | 1 | 1 | 2 |
| Reporting | 0 | 2 | 3 | 5 |
| Research | 5 | 14 | 20 | 39 |
| SLA / TPAs | 0 | 0 | 0 | 0 |
| Storage | 4 | 8 | 9 | 21 |
| Testing | 1 | 1 | 3 | 5 |
| Response Time | | | | |
| Days | 7 | 4 | 3 | 4.67 |
| % enquiries responded to within 20 days | 91% | 100% | 100% | 97% |

Annex B**HTA quarterly enquiries report 2010/2011 financial year****Overview of enquiries by quarter**

| | Quarters | | | | Year |
|------------------------|-----------------|------|-----|-----|-------------|
| | Q1 | Q2 | Q3 | Q4 | Total |
| Total | 1318 | 1131 | 735 | 923 | 4107 |
| Media | 27 | 26 | 20 | 19 | 92 |
| Professional | 354 | 339 | 298 | 336 | 1327 |
| Public | 230 | 152 | 105 | 209 | 696 |
| Channel | | | | | |
| Email | 402 | 321 | 262 | 333 | 1318 |
| Face -to-Face | 1 | 1 | 1 | 0 | 3 |
| Phone | 826 | 739 | 419 | 552 | 2536 |
| Post | 89 | 68 | 53 | 38 | 248 |
| Web | 0 | 2 | 0 | 0 | 2 |
| Subjects | | | | | |
| Anatomy | 16 | 13 | 9 | 9 | 47 |
| Body Donation | 861 | 701 | 392 | 537 | 2491 |
| Bone Marrow Donation | 0 | 4 | 1 | 0 | 5 |
| Business and Strategy | 0 | 0 | 0 | 1 | 1 |
| Communications | 4 | 5 | 17 | 4 | 30 |
| Complaints | 1 | 0 | 0 | 3 | 4 |
| Consent | 15 | 14 | 21 | 13 | 63 |
| Directions | 1 | 0 | 0 | 0 | 1 |
| Disposal | 20 | 15 | 9 | 6 | 50 |
| DNA | 10 | 17 | 11 | 14 | 52 |
| Enquiries | 0 | 3 | 4 | 1 | 8 |
| Ethics | 5 | 5 | 2 | 1 | 13 |
| Fees | 1 | 3 | 2 | 4 | 10 |
| Finance | 2 | 4 | 3 | 5 | 14 |
| Freedom of Information | 3 | 3 | 2 | 23 | 31 |
| Governance | 1 | 1 | 0 | 1 | 3 |
| HR | 2 | 0 | 0 | 1 | 3 |
| Human Application | 53 | 40 | 56 | 56 | 205 |
| Import and Export | 11 | 14 | 11 | 15 | 51 |
| Inspections | 2 | 5 | 2 | 2 | 11 |
| IT | 5 | 0 | 4 | 13 | 22 |

| | | | | | |
|---|------|------|--------|--------|--------|
| Knowledge and Quality Management | 5 | 1 | 2 | 4 | 12 |
| Legal Advice | 0 | 2 | 0 | 1 | 3 |
| Legislation | 8 | 9 | 5 | 8 | 30 |
| Licensing | 89 | 96 | 76 | 71 | 332 |
| Organ Transplants | 29 | 21 | 11 | 23 | 84 |
| Parliamentary Questions | 0 | 5 | 6 | 1 | 12 |
| Post Mortem | 91 | 73 | 39 | 41 | 244 |
| Public Display | 6 | 6 | 5 | 8 | 25 |
| Reporting | 3 | 0 | 4 | 3 | 10 |
| Research | 54 | 51 | 33 | 30 | 168 |
| SLA / TPAs | 5 | 9 | 5 | 3 | 22 |
| Storage | 11 | 8 | 6 | 18 | 43 |
| Testing | 4 | 3 | 1 | 3 | 11 |
| Response time | | | | | |
| Days | 7.33 | 9.67 | 7.33 | 6.33 | 7.67 |
| % enquiries responded to within 20 days | 94% | 93% | 93.33% | 97.33% | 94.42% |