

Forty-eighth Meeting of the Human Tissue Authority

Date 22 March 2011
Time 10.30am – 1.00 pm
Venue The Westminster Conference Centre
 1 Victoria Street
 London, SW1H 0ET

Agenda

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

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 25 January 2011 HTA (11/11)
4. Matters arising
5. Chair's report Oral
6. ALB review and shared services update (I) HTA (12/11) CM
7. Statutory approval in cases where directed donation cannot take place (D) HTA (13/11) SG
8. Post mortem tissue retention in Home Office cases (D) HTA (14/11) AC
9. HTA Strategic Plan 2011 to 2014 and Budget and Strategic Performance Review 2011/12 (D) HTA (15/11) AMS
10. Communications Strategy 2011-2013 (D) HTA (16/11) SG
11. Strategic performance review February 2011 (I) HTA (17/11) AMS
12. Financial report February 2011 (I) HTA (18/11) SM
13. Report from the Audit Committee February 2011 (I) HTA (19/11) SM
14. Enquiries report December 2010 to February 2011 (I) HTA (20/11) SG
15. Any other business

Minutes of the forty seventh meeting of the Human Tissue Authority

Date 25 January 2010
Venue The Westminster Conference Centre
 1 Victoria Street
 London
 SW1H 0ET

Present

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 Keith Rigg
 Ms Catharine Seddon

In attendance

Mr Craig Muir (Chief Executive)
 Dr Alan Clamp (Director of Compliance and Enforcement)
 Dr Shaun Griffin (Director of Communications and Public Affairs / Interim Director of Policy)
 Mrs Sue Martin (Director of Resources)
 Mr Allan Marriott-Smith (Authority Secretary)
 Miss Ariel Armarego-Marriott (Resources Assistant)

Observers

Mr Edward Webb (Department of Health)
 Mr Patrick Irwin (Department of Health)

Item	Title	Action
Item 1	Welcome and apologies	
	<ol style="list-style-type: none"> 1. Baroness Warwick welcomed Members and observers to the forty-seventh meeting of the Human Tissue Authority. 2. Apologies had been received from Dr Andrew Reid. 	
Item 2	Declarations of interest	
	<ol style="list-style-type: none"> 3. There were no declarations of interest. 	
Item 3	Minutes of 23 November 2010 [paper: HTA (01/11)]	
	<ol style="list-style-type: none"> 4. The minutes of 23 November 2010 were adopted. 	
Item 4	Matters arising	
	<ol style="list-style-type: none"> 5. All actions from the previous meeting had been fulfilled or were in hand, with the exception of the paper on issues stemming from PACE and the Coroners Rules. This will be deferred to the March Authority meeting as Dr Reid could not be present at the January Meeting. 6. There has still been no formal decision on which body will become the Competent Authority for the Organ Donation Directive. The Executive is undertaking business planning on the basis that the HTA will take the role. 7. Following the oral report at the last meeting regarding the public position taken by the British Medical Association (BMA) on the ALB review, a meeting had taken place between HTA and BMA representatives. Shaun Griffin provided the Authority with an oral report on the outcome of the meeting which had been useful in reaching a shared understanding of the issues at stake, but did not change the BMA's position. 	
Item 5	Chair's report	
	<ol style="list-style-type: none"> 6. The Chair thanked Professor Banner for deputising as Chair during her absence in December. 7. The Chair informed Members that she had held further discussions with Professor Lisa Jardine at the Human Fertilisation and Embryology Authority (HFEA) to discuss issues of common interest in relation to the Arm's Length Body (ALB) review. A meeting had also taken place with Mark Bale and Tedd Webb from the Department of Health, also to discuss the implications of the ALB review. 8. The Chair had also attended a Peers meeting at the House 	

	<p>of Lords organised by Earl Howe to discuss issues raised by the ALB review for the HTA and the HFEA.</p> <p>9. The Chair invited Craig Muir to provide the Authority with a summary of the recommendations of the Academy of Medical Science's review of research regulation. In general the report was favourable about the role played by the HTA. The report had been mistaken on a number of issues concerning the HTA's approach to regulating certain materials, this position would be clarified. The report recommended a single research regulator; a conclusion which the Executive believes will not deliver the benefits envisaged by the Academy in relation to the regulation of human tissue.</p> <p>10. The Welsh Assembly Government has been consulting on the issue of presumed consent in organ donation for people who live and die in Wales. Members had been provided with a copy of the HTA's response to the consultation.</p> <p>11. The Chair asked Members to note that she had taken the decision to combine the public Authority meeting with the annual review event. As a result, the next public Authority meeting will take place in July.</p>	
Item 6	Strategic Performance Review December 2010 [paper: HTA (02/11)]	
	<p>14. Allan Marriott Smith introduced the paper which described the HTA's performance against Key Performance Indicators (KPIs). He drew particular attention to the activity undertaken by the Staff Survey Working Group (SSWG) to identify the issues which contribute to staff turnover and the actions which are being taken as a result.</p> <p>15. Two issues were discussed.</p> <p>i. Five posts are currently being actively recruited. Following the arrival of the new Director of Compliance and Enforcement, the Executive is reviewing the organisational structure. As part of this review, a decision will be taken on how many of the other currently vacant posts will need to be filled. Craig Muir assured Members that, while a number of operational pressure points exist, current staffing levels are sufficient to undertake business critical activity. This has been possible by achieving efficiencies in business operations.</p> <p>ii. Members expressed concern that compliance information was not being received from establishments within required timescales. This will be a topic for discussion at the next Regulation Members' Group meeting.</p>	

	Action: Authority Members to be copied in on the staff newsletter for information.	SG
Item 7	Financial Report December 2010 [paper: HTA (03/11)]	
	<p>16. Sue Martin introduced the paper, which described the financial position as at the end of December 2010.</p> <p>17. Authority Members sought clarification on two issues.</p> <p>i. The position described in paragraph 17 of the paper, relating to the reduction in the number of licences, is thought to be associated with establishments rationalising the number of licences they hold.</p> <p>ii. Members asked for clarification on the variance shown in Annex B relating to income from devolved administrations,</p> <p>18. The paper was accepted for information.</p> <p>Action: Members to be provided with an explanation for the variance shown in Annex B relating to income from devolved administrations,</p>	SM
Item 8	Criteria for judging ALB review options [paper: HTA (03/11)]	
	<p>19. Craig Muir introduced the paper which had been produced at the request of the Authority at its November meeting and set out a range of criteria against which options for the transfer of the HTA's functions can be judged. In making an assessment of the various options, the Executive had concluded that the criteria would best be met by keeping the HTA's functions together as a single entity.</p> <p>20. In discussion, a number of themes emerged:</p> <p>i. Keeping the HTA's functions together in a single entity garnered unanimous support from the Authority as the transfer option that best met the criteria.</p> <p>ii. Several Members expressed reservations about the CQC being the appropriate body to receive the HTA's functions. Two specific concerns were put forward: the different styles of regulation which are adopted by the HTA and the CQC; and a weakening of accountability in the regulation of human tissue as a result of both the scale of the HTA relative to the CQC and the relative priorities within CQC as its remit expands.</p> <p>iii. Concerns were also voiced on the issues associated with sharing services with the CQC. Costs, risks and accountability issues will all require careful consideration.</p> <p>iv. Members were keen to know more about the views of patient groups on the transfer options.</p> <p>21. Members agree to adopt the criteria and endorsed the single</p>	

	<p>entity approach as being the organisational model that will best meet the criteria.</p> <p>Action: In meetings with Ministers and the Department of Health the “all functions” approach will be vigorously pursued.</p> <p>Action: An update on the approach to shared services will be brought to a future Authority meeting.</p>	CM
Item 9	Findings from the audit of post-mortem establishments [paper: HTA (05/11)]	
	<p>22. Alan Clamp introduced the paper which described the progress made with the audit of post-mortem establishments which had been undertaken following the issue of General Directions in April 2010. Data quality issues and the need for follow up with a number of establishments had delayed progress with producing the report.</p> <p>23. A number of points were made during the discussion.</p> <p>i. The Authority will need to see more detailed results before the benefits of undertaking the audit can be properly understood.</p> <p>ii. The Association of Chief Police Officers (ACPO) has also commissioned an audit of retained material from the same establishments. Members noted the risks associated with the HTA and ACPO audits reaching significantly different conclusions. Communication of the findings of both audits will be coordinated by a Gold Group on which the HTA is represented.</p> <p>iii. If unresolved retention issues remain following data quality checks, the relevant establishments must be prioritised for further investigation and swift and appropriate regulatory action if this proves necessary.</p> <p>iv. Concerns were expressed that two establishments have failed to supply audit information.</p> <p>v. Strategic focus on the standards in the post mortem sector must be maintained during any transition resulting from the ALB review.</p> <p>Action: The Executive will provide Members with an update on the key findings from the audit by the end of February 2010.</p> <p>Action: The full report from the audit will be presented at the March Authority meeting.</p>	<p>AC</p> <p>AC</p>
Item 10	Significant regulatory activity report – 1 October to 31 December 2010 [paper: HTA (06/11)]	
	24. Alan Clamp introduced the paper, which is a regular item	

	<p>which sets out the significant regulatory action undertaken by the HTA in the quarter ending December 2010.</p> <p>25. The Authority considered the content of the report and made a number of comments:</p> <ul style="list-style-type: none"> i. Members expressed concern that 24 hour reporting of Serious Adverse Events and Reactions (SAEARs) was significantly below target. This poses a potential risk to the HTA reputation, if a serious adverse event is reported by the media before the HTA has been informed. ii. There are likely to be varying degrees of the severity of SAEARs and Serious Untoward Incidents (SUIs). Those with potential to affect patient safety being the most serious. Further explanation is required on the rationale for 24 reporting in all cases. <p>Action: The Executive will look into the basis for reporting of all SAEARS within 24 hours and will consider ways to ensure establishments meet this standard.</p> <p>Action: The Executive will convene a meeting of the Regulation Members' Group to work through the approach to reporting significant regulatory action. This will take place before the next report comes to the May Authority meeting.</p>	<p>AC</p> <p>AC</p>
Item 11	Summary of post-inspection feedback from 2010 [HTA (07/11)]	
	<p>26. Alan Clamp introduced the paper, which presented the feedback from establishments on the inspection process.</p> <p>27. Members welcomed the positive messages set out in the report. They also stressed that establishments should be strongly encouraged to complete feedback forms to ensure that the HTA can improve its regulatory processes.</p> <p>Action: Future reports should, if possible, include an indication of the number of responses which were received anonymously.</p>	<p>AC</p>
Item 12	Domino paired living organ donation [HTA (08/11)]	
	<p>28. Shaun Griffin introduced the paper which set out the proposals for the approval of domino paired living organ donation.</p> <p>29. Members discussed a number of issues raised by the paper and approved the recommendation that these cases be referred to a panel for a decision.</p> <p>Action: HTA will develop a policy and procedure for organs that cannot be transplanted into the intended recipient.</p>	<p>SG</p>

Item 13	HTA policy on composite tissue (09/11)]	
	30. Shaun Griffin introduced the paper. 31. The Authority accepted the paper for information and expressed the view that consistency across the EU in definitions should be an important consideration in the next steps.	
Item 14	Operation of the living organ donation system (10/11)]	
	32. Shaun Griffin introduced the paper, the first in a new style of quarterly reporting to the Authority. 33. The Authority accepted the paper for information.	
Item 15	Update in non-genetically or emotionally related directed donation (Oral report)]	
	34. Shaun Griffin provided an oral report on the project which has been established to look into the assessment of directed organ donation in cases where the donor and recipient are neither emotionally nor genetically related. 35. An independent assessment working group has been established to oversee this work. The group will be chaired by Craig Muir and Catharine Seddon, Suzanne McCarthy and Keith Rigg would be invited to provide Member input. The group will meet next after the Authority meeting in March.	
Item 16	Any other business	
	Action: The Executive will provide a full list of the Authority's committees and groups and their membership to Members.	AMS

The meeting closed at 1.00 pm

Authority paper

Date	22 March 2011	Paper Reference	HTA (12/11)
Agenda item	6	Author	Sara Coakley

ALB review and shared services update

Purpose of paper

1. The purpose of the paper is to provide the Authority with an update on the latest issues arising from the review of arm's length bodies (ALBs) and developments on the shared services agenda since its last meeting.

Action

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

Progress in Parliament and elsewhere

3. Since the last Authority meeting there has been a specific hour long debate (Grand Committee) on the Human Fertilisation and Embryology Authority (HFEA) and the HTA, and three Committee stage debates in the main chamber.
4. Although Schedule 7 of the Bill has been withdrawn by the Government, there have been no substantive changes to the legislation as it affects HTA. The Government has shown some ambivalence about the Academy of Medical Sciences proposals for a new health research regulator and Department of Health (DH) Ministers and officials have shown sympathy for our arguments that all the HTA functions should be kept together. The Government has said proposals will only be implemented once decisions on all the functions, including research have been taken. The consultation on proposals for the HTA and HFEA have moved back to late summer, and the Government now seem to be working to a timescale for implementation of 2014 at the earliest.
5. A summary of the Parliamentary debates is included in the Annex.

Developments with the Care Quality Commission

6. SMT met with the Care Quality Commission (CQC) on 11 February. The aim of the meeting was to:
 - decide how we could work together in the light of the ALB proposals;
 - understand each others' positions on the ALB review;
 - identify potential areas of synergy which we could explore further;
 - pursue those synergies which might be mutually beneficial and which would not pre-empt any decisions on the ALB review.
7. The meeting was very helpful. The two organisations agreed to meet again shortly to take forward work on priorities for capitalising on synergies between the two organisations.
8. We have also been working with CQC and DH to share understanding of our functions under the Human Tissue Act. This will inform a consultation planned for late summer 2011 on where those functions would best transfer.

Other stakeholders

9. On 4 February Diana Warwick wrote to a selected number of 'new' public group stakeholders seeking their opinions on our functions and how our work might impact upon what they do.
10. Two letters were published in national newspapers calling for the HTA to remain as it is. A letter was published in the Sunday Times on 20 February from medico legal academics, and another in the Guardian on 4 March from consultant surgeons.
11. On the 7 March a letter from Diana Warwick and a briefing was sent to 120 Lords who were taking part in the Public Bodies Bill debates.

Shared services

12. The Department of Health's Business Shared Services Transformation (BSST) programme is underway. Transactional work on HR and Finance (e.g. payroll, record keeping, processing and paying invoices) will be the first areas to be shared. The programme applies to all ALBs and the Department of Health (DH). The HTA will be expected to participate regardless of ALB changes.
13. The HTA is in discussion with CQC and HFEA to explore how we take this forward together. We will be meeting DH and CQC in April to review progress.

14. The feedback from the DH finance due diligence exercise (to propose in detail what might be shared by all DH bodies) has been delayed slightly and is likely to take place around the end of March. The reports to DH on the final proposals for finance and HR are expected in April. These should give us greater clarity about the implications for the HTA, although details and timing will need to be worked through.

Annex – Summary of Parliamentary debates

Grand Committee debate - 1 February

1. The debate was secured by Labour peer and opposition spokesperson Baroness Thornton, the purpose was “to ask her Majesty’s Government how they will maintain public confidence and patient safety following the abolition of the HFEA and the HTA”.
2. The 10 speakers included Baroness Warwick, and the parliamentary under secretary of state for the Department of Health (Earl Howe) responded on behalf of the government. It was an interesting debate with most Peers airing their frustration about the speed and scale of the Public Bodies Bill, the lack of consultation, revisiting this issue so soon after the Regulatory Authority for Tissue and Embryology (RATE) proposal was dropped, and the importance of retaining the HTA and HFEA to ensure public confidence. We believe this was the only special debate arranged relating to any of the 175 ALB’s in the Bill.

Public Bodies Bill Committee Stage - 28 February

3. Lord Taylor of Holbeach (government spokesperson) announced a number of significant issues in relation to the Bill; Amendment 175 called for safeguards over ministerial powers to be introduced, Lord Taylor said he intended to reach a solution with peers that would offer further protection and would ensure the Bill is proportionate. He removed Schedule 7 of the Bill which listed around 150 ALBs including the HTA, due to “strong feelings” aired across the House because it represented “a significant delegation of power to Ministers and has the potential to hinder the independent delivery of public functions”. He also stated that any clause contained within the Bill relating to the public forest estate would be removed following a statement made in the lower house on 17 February.
4. Schedule 7 of the Bill was the section that allowed government to modify the functions of, or abolish, any of the bodies in this Schedule. The HTA is still in Schedule 5, which allows our functions to be transferred, abolished or modified in some other way. We believe this means that if our functions were transferred elsewhere as a whole entity, there would remain a shell Authority which would need, for tidiness, to be abolished in due course by another Bill.
5. Their Lordships went on to debate 14 ALBs listed in Schedule 1. All ALBs had an amendment attached to remove them from the bill. All amendments were either ‘not moved’ or ‘withdrawn’.

Public Bodies Bill Committee Stage - 7 March

6. The Lords debated this stage without great drama: all amendments were either 'not moved' or 'withdrawn' and some were passed with agreement to restrict ministerial powers. Schedule 1 was completed and they debated Schedules 2, 3 and nearly all of Schedule 4.

Final Committee stage of Public Bodies Bill - 10 March

7. There was an hour long debate around the amendments to remove the HFEA and the HTA from Schedule 5 of the Bill. Schedule 5 proposes to grant ministers powers to modify or transfer functions of thirteen Arms Length Bodies. The HTA amendment was proposed by Baroness Thornton, Lord Warner and Lord Willis of Knaresborough.
8. There was a consensus across all benches that both these bodies do sterling work:
- “Change should be helpful in achieving the broader stated aims of reducing bureaucracy and saving money rather than simply focusing on a reduction in the number of arm’s-length bodies....I believe that both bodies have succeeded in making improvements in their work and functions in recent times” Baroness Thornton.
 - “I ask the Government to consider whether it really makes a lot of sense to transfer even more functions to the CQC from two well established licensing systems.....the brands of these two bodies are very strong among the public and in a lot of other areas and they have many powerful supporters” Lord Warner.
 - “The government have failed to present a convincing argument for changing from two well respected regulators” Lord Willis of Knaresborough
 - “We have not yet been given good reasons why these two functioning bodies should be got rid of....I say that these two organisations appear to work and so it is premature, at least, to be abolishing them now” Baroness Butler-Sloss.
 - “The HFEA and the HTA are models of regulatory authority that were right for the times in which they were created and which have done an admirable job in meeting the demands placed on them” Earl Howe.
9. A history lesson on why and how we were both set up informed the debate regarding the now proposed direction of travel. Concerns were aired about separating the functions of both bodies, and expressed frustration given the amount of time and effort that was put into our creation in the first place. In response, the government argued that “times change” and that there is “a clear objective to streamline the process of regulation and consequently, reduce costs

and the administrative burden on establishments while continuing to offer the necessary protection for the public” (Earl Howe).

10. Some were concerned about the capability of the CQC to take on yet more functions so soon after assuming others and so near to taking on a lot more. They questioned their expertise, or lack of it, in such complex areas: “there is a huge difference between inspecting care homes and inspecting clinics” (Lord Willis of Knaresborough). The government responded by assuring noble Lords that the CQC “will be given the capacity and the resources to carry out any widened functions and that it is envisaged that expertise will follow functions; for instance, through staff transfers and expert reference groups” (Earl Howe). He also pointed out the CQC has previous experience in taking on the functions of a specialist regulator – the Mental Health Act Commission.
11. Earl Howe said that there would no piecemeal transfer of functions to various bodies. The proposals would be implemented once decisions on all the various elements had been taken. This is dependent on decisions on the Academy of Medical Sciences recommendation to establish a new Health Research Agency. The Government has not yet responded to the proposal and there have been some ambivalent Government statements on the setting up of a research regulator. If a new regulator were created on the lines recommended, it would require new primary legislation in a second session Bill.
12. The development timetable will deal with consultations (now due late summer 2011) on the functions of the HTA and HFEA, including our research functions. Earl Howe promised Lords that he would write to them and set out a clearer timetable. The sense is that 2013 is now looking very challenging, with 2014 being the earliest likely transfer date.
13. In response Baroness Thornton said she was still unsure about a lot of things, stating that the minister “has given us a great deal to think about” and that she will discuss this further before the Report stage (due 23 March). She therefore decided not to press her amendment to the vote and withdrew it.

Authority paper

Date	22 March 2011	Paper Reference	HTA (13/11)
Agenda item	7	Author	Pamela Sandler

Statutory approval in cases where directed donation cannot take place

Purpose

1. This paper's recommendations only apply to cases where it is discovered that the organ cannot be transplanted to the intended recipient after they have been anaesthetised.
2. This paper is drafted to meet the policy requirements of paragraph 18 of the legal advice at Annex A.

Background

3. In late 2009 the HTA received a phone call from James Neuberger, Associate Medical Director at NHS Blood and Transplant (NHSBT), who had been contacted by a surgeon. The surgeon had removed a kidney from a living donor and had subsequently discovered the recipient was not suitable for transplantation (because they had previously undiagnosed cancer).
4. In this case, without having a precedent, we suggested that the donor's family were asked what should be done with the organ. They decided that the kidney should be re-implanted, which is what happened.
5. When the Executive has been alerted in advance that if the planned transplant cannot take place a potential living donor has consented for their organ to be transplanted into an alternative unknown recipient, we advise that the Independent Assessor (IA) undertakes both a directed and a non-directed altruistic assessment, and submits two reports to the HTA

6. The Executive then assesses the directed case and refers the non-directed altruistic case to a panel of three Authority members. This ensures appropriate HTA approval is given for both eventualities. There have been two cases since 2006 which have required dual approvals.
7. Whilst it is a very rare situation that an organ cannot be transplanted into the intended recipient, these cases could prove a significant reputational risk to the HTA as the organ may be perceived to be wasted when it could in fact have successfully been implanted into an alternative recipient.
8. This matter was discussed at Transplantation Working Group (TWG) in December 2010 where NHSBT representatives and Keith Rigg highlighted the potential reputational risk to the HTA and NHSBT, and the need for a Policy to be put in place as a matter of priority.

Current position

9. When such exceptional situations arise, we currently advise that the organ is re-implanted in the absence of known wishes.
10. If the organ cannot be implanted into the intended recipient there are four potential options:
 - a. the organ can be re-implanted into the donor;
 - b. it can be disposed of;
 - c. it can be used for research; or
 - d. it can be transplanted into an alternative recipient.
11. However, the last two options are dependent on whether or not the donor had consented to either of these options before surgery. Option d requires that the necessary HTA process has been followed and the correct approval given.
12. As we do not actively seek the donor's secondary consent at present, if a living donor organ cannot be transplanted into the intended recipient and the donor has not made a decision on what should happen, then the organ must be re-implanted into the donor or, if this is not possible, disposed of.
13. The HTA cannot approve transplantation of the organ into an alternative recipient, without the donor's consent.
14. If the donor has indicated that they wish for the organ to be re-implanted, used for research or disposed of, it is the responsibility of the surgical team to take this forward and no further input is required from the HTA.

Legal advice

15. Legal advice has been sought and HTA's Head of Legal has drafted a paper which sets out the possible options available to the HTA for dealing with these cases. See Annex A.
16. This paper provides the proposed policy position as required by paragraph 18 of Annex A. However agreement to delegate the decision making functions is required before we can move forward and draft a formal policy based on this paper.
17. Our legal advice is that it would be appropriate to interpret Regulation 12(5) together with Schedule 2, as allowing a formal delegation of the approval for the use of non-directed donation in cases where the secondary intention is to donate altruistically, from the Authority to the Executive.

Proposed policy position

18. The Executive recommends that all living donors are asked to consider this issue and to make a decision before the donation.
19. If a living donor has made a decision on what should happen to their organ if it is unable to be transplanted into the intended recipient, this decision should be clearly documented in the patient's records.
20. The HTA is only involved in the process where consent is given for the organ to be transplanted into an alternative recipient.
21. In the event that the organ cannot be transplanted into the intended recipient and the recipient wishes for their organ to be redirected, then HTA approval for the donation must be obtained. NHSBT would allocate this organ, which would be directed to the most appropriate person on the deceased donor waiting list. As the donor would have no relationship with the recipient, this would become a non-directed altruistic donation.
22. A consent form has been drafted (Annex A) to reflect which option is preferred by the donor. The Living Donor Coordinator would speak to the donor about their choices and a factsheet would be provided by the HTA. The IA would document the donor's decision and this form would be retained with the clinical notes, as it is the surgeon who would need to refer to it in the event that the directed transplant cannot proceed.
23. The HTA's Online Submission System (OSS) will need to be amended to include an additional section on the form to ensure the HTA is aware of cases where the donor wishes to redirect their organ to the deceased donor pool in the event that it cannot be transplanted into the intended recipient. In these cases, two approval notices will be generated; one to approve the directed donation and another to approve the non-

directed donation. These notifications will be sent to the Independent Assessor/Living Donor Coordinator and NHSBT.

24. Engagement with surgeons and the transplant community will be required to ensure all surgeons are aware that Section 33 of the Act states that it is an offence to remove transplantable material from a living person, or to use material for transplant to a living person without consent for such scheduled purposes. Further communication with surgeons and the transplant community would be necessary to ensure they are aware of the changes to the HTA approval processes and to highlight the fact they would be committing an offence if they redirected an organ without the consent of the donor.

Recommendations

25. It was suggested at TWG (December 2010) that a significant proportion of people would opt to redirect their organ altruistically, in the event that it could not be transplanted into the intended recipient. If this is the case, and we required these cases to be assessed by a Panel of at least three Authority Members we would need to put in place a process for dealing with a likely five-fold increase in Panel cases, at the very least, based on advice from TWG Members.
26. As incidents of this nature are very rare, it would be disproportionate for the Authority to assess each case, as they would be highly unlikely to end in a non-directed altruistic donation.
27. Our legal advice states that the Regulations can be interpreted in such a way that when the primary intent of the donor is to direct their donation, the secondary decision to donate altruistically does not require Authority consideration.
28. It is recommended that the Authority delegate the function of statutory approval of non-directed altruistic donations, where the primary motive is directed donation, to the Executive.
29. We further recommend that a psychiatric/psychological report is not required when non-directed altruistic donation is not the primary purpose.

Next steps

30. If this function is delegated to the Executive, we will proceed with changes to the web form, Online Submission System (OSS) and communicate this change to surgeons and the transplant community. We will draft a policy to support this process.
31. We will aim for the system to be operational by early May 2011. An outline delivery plan is attached at Annex B.



HTA (13-11) Statutory approval in cases where directed donation cannot take place - Annex A

Date 4 March 2011

Author Helen Holmes

Legal Advice

Living Donation - options for donors where directed donation cannot take place

Options where directed donation cannot take place

1. In the majority of cases where a directed donation takes place, the surgery proceeds as planned. However, the Human Tissue Authority (HTA) is aware of two cases that raise the prospect that in a very small proportion of cases (about 1 in 1500) the planned transplant cannot proceed and this is only discovered during surgery.
2. If the intended donation cannot take place during surgery, the HTA has identified four possible options for use of the organ:
 - a) re-implantation
 - b) disposal
 - c) research
 - d) transplant to an unnamed recipient, allocated to the national transplant list
3. Neither the Human Tissue Act 2004 (the Act) nor the Regulations¹ have provided for these legal options. It may be that such situations were not contemplated at the time either the Act or the Regulations were passed.

Consent from the donor

4. In the first three situations (re-implantation, disposal and use for research) the donor's consent is a matter for discussion between the donor and the surgeon. It is not a matter that requires approval from the HTA, although the HTA can

¹ The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplant) Regulations 2006 (SI 2006, no 1659)

provide guidance. Where a surgeon proceeds to redirect an organ without consent this may be a criminal activity under s.5 of the Act.

5. In the situation where transplant to an unnamed recipient is the wish of the donor, consent from the donor and statutory approval from the HTA are both required.

Legal framework – the criminal offence

6. Section 33 of the Act creates two offences - one relates to the removal of transplantable material from a living person, and the other is concerned with the use of material for transplant to a living person. s.33 (3) allows exceptions to those offences through Regulations made by the Secretary of State.
7. The Regulations created under s.33 (3) are contained in Part 3 of the Regulations. Regulations 11-12 create the process for approval of living donation of transplantable material.
8. Under Regulation 11(1), the donor's doctor refers the matter to the HTA. Under Regulation 11(3), the HTA must be satisfied that:
 - (3)(a) no reward has been or is to be given;
 - (3)(b)(i) consent for removal of the transplantable material has been given; and
 - (3)(b)(ii) removal for transplant is otherwise lawful.
9. Under Regulation 11(4) the HTA must take into account the report of the separate interviews with the donor and recipient, (each report to include any evidence of duress or coercion affecting the consent, evidence of an offer of a reward, and how any communication difficulties were overcome. The report from the interview with the donor must, in addition, cover information about medical risk, and the capacity of the donor to understand the clinical risk and to understand that consent can be withdrawn at any time (Regulation 11(8)-(9)).

Approval by a panel of Authority members

10. Regulation 12 specifies cases where approval must be made by at least three Authority members. One of the three groups defined in this category covers non directed altruistic donations, defined in Regulation 12(5) as "the removal of transplantable material from a donor for transplant to a person who is not genetically related to the donor or known to him."
11. In all cases requiring approval under Regulation 12, a panel of three Authority members must be satisfied that the requirements of Regulation 11 are met. Any failure to follow the prescribed decision making procedure would open the

Authority to the risk of either a request for reconsideration under Regulation 13, or judicial review.

Options for approval - Authority panel

12. Where the donor identifies a recipient but requests that in the event the organ cannot be used for that person, it is donated to an unknown person in clinical need, there may be two ways of interpreting the Regulations. Whichever way is preferred will then provide the basis on which the HTA provides approval either from the Executive or by a panel of Authority members.
13. The most straightforward reading of Regulation 12(5) would suggest that the secondary use is given approval by a panel of no less than three Authority members. This is on the basis that a panel must approve cases where the donor's primary intent is to donate as a non directed altruistic donation. This would have the practical effect of requiring that the Executive carry out their own scrutiny of the matters in Regulation 11 for the directed donation, and then refer the "residual" cases to a panel for approval. Given that the main scrutiny will already have taken place, the panel would be able to provide approval of these cases in relatively short order because the prime motive for the transplant is directed.
14. There are practical issues arising in this option for the Authority. While it is not possible to put an exact figure on the number of "residual" cases, the advice given by members of the Transplant Working Group (TWG) was that it would be a significant proportion of the 100+ reports received each month. At present Members consider about 10 cases per month; a significant increase in this number would cause practical issues for both Authority members and the Executive, and the risk of a backlog of cases would be high.

Options for approval - Executive approval

15. One alternate interpretation of Regulation 12(5) may be capable of allowing approval for the secondary use of non-directed altruistic donation by the Executive. This approach is a provisional legal view, and should be treated as such. Regulation 12(5) is intended to cover cases where the removal of transplantable material is for the purpose of transplantation to a person not known or genetically related to the donor². It *may* be possible to interpret that

² See for example, para 7.7 of the Department of Health Explanatory Memorandum for the Regulations "the Department has ultimately decided upon a position that Human Tissue Authority approval is needed in situations involving (i) child donors, (ii) adults who are not capable of giving consent, and (iii) competent adults donating organs or part organs...In all cases requiring approval, the HTA must be satisfied that no reward has been given for the donation, that proper consent has been obtained and that the procedure is otherwise lawful. In cases of greater complexity, the decision to approve the donation must be made by a panel of at least three members of the HTA.

Regulation 12(5) applies to cases where the primary *intent* of the donor is for a non-directed donation. The Regulations do not deal with the issue of approval for a secondary use of donation. If the policy intent of the Regulation was to ensure scrutiny by Authority members of the primary intent of the donor, and does not deal with the prospect of the secondary use, it may be possible to read down the Regulations in a manner that does not create a dual system of approval. Where the donor has identified the recipient and fully intends that the transplantable material goes to the named recipient, then HTA statutory approval for the secondary use will still be required but may not need to be provided by a panel of Authority members.

16. As such, it may be the situation, that where the intended directed donation cannot take place, Regulation 12(5) does not have to apply to cases where a form of residual approval is given in the event that the main intent of the donor cannot be fulfilled.
17. If this approach warrants further consideration, then further assistance may be provided by Schedule 2, paragraph 21 of the Act. This provides that the Authority “may delegate any of its functions (to such extent as it may determine) a) to any member of the Authority b) to any member of the staff of the Authority, or c) to a committee consisting of persons each of whom is (i) a member of the Authority or (ii) a member of staff of the Authority”. Such an interpretation is novel, and the HTA would benefit from a second legal opinion if this option for progress is the one preferred by the Authority.
18. The use of the alternate interpretation of Regulation 12(5) together with Schedule 2, paragraph 21 would allow for a formal delegation of the statutory approval for the residual use of non-directed donation from the Authority to the Executive. This would be required as a formal policy so that the Authority is clear about the extent of its delegation, the circumstances, and the formal process of notification if such an event does take place.

Consent form

19. A draft consent form in outline is attached. The consent form stating which residual option is preferred by the donor should be retained with the clinical notes as it is the surgeon who would need to refer to this in the event that the directed transplant cannot proceed. It may be useful for the donor and surgeon to each sign and date this consent form. The surgeon lacks the legal ability to make the decision about the use of the organ - the decision is one that only the donor can make. This form provides protection and clarity for the surgeon to act in accordance with clear consent from the patient. For those cases where secondary HTA approval is needed, there is a single document to show this which acts as an audit tool for the HTA, the clinical team, and the donor.

20. It would be possible to amend the Online Submission System (OSS) to allow the Independent Assessor (IA) to indicate when a donor has consented to transplant to an unnamed recipient, so that the HTA can ensure that approval is sought for cases where the donor wishes the transplant to an unknown recipient as a residual option. The original form would be retained with the donor's clinical notes. The HTA will need to consider whether a copy of that form is required where the secondary approval is required to support the OSS submission from the IA.

Draft consent form

Patient details

Surgeon details

My name is ... and I am the donor of an organ [specify which organ] which is intended for recipient [name of recipient].

I understand that in a very small minority of cases, it may not be possible for the surgeon to transplant my organ once surgery begins. In that situation, I wish the following to take place

1. donate the organ to another living person with clinical need for the organ
2. re-implant the organ
3. dispose of the organ
4. donate the organ for the purpose of research
5. other [please specify the detail]

Name of donor

Signature

Date

Name of surgeon

Signature

Date



Outline delivery plan

Action	External body/bodies to be involved	Deadline
Take Authority paper, legal advice and process plan to Regulatory Policies Group (RPG) for feedback.		16 March
Seek delegation from the Authority on the Executive's request for the function of statutory approval in cases where an organ cannot be transplanted into the intended recipient. Sign off the process plan.		22 March
Interim guidance to NHS Blood and Transplant (NHSBT).	NHSBT	24 March
Agree the draft model consent form for the Living Donor Coordinator (LDC) to use to document the donor's choice.	NHSBT	29 March
Initiate update to the HTA Online Submission System (OSS) to allow the donor's wishes to be recorded by the Independent Assessor (IA). N.B. This will involve adding an additional question to the online form the IA completes. The HTA will only be informed when the donor has decided to redirect their organ to the deceased donor pool.	IT company, transplant units, IAs and NHSBT	12 April

Initiate changes to the OSS to ensure dual notifications can be sent for the primary directed donation and the secondary non-directed donation where appropriate.	IT company, transplant units, IAs and NHSBT	12 April
Produce factsheet for transplant units to inform donors of the options available.	(To go to TWG)	13 April
Update on progress and draft communications for IAs and Units to the Transplant Working Group (TWG).	(To go to TWG)	13 April
Training update to IAs and notification to surgeons of the offence committed in redirecting an organ without consent of the donor.	Transplant units and IAs	15 April
Update to the Senior Management Team (SMT).		21 April
OSS changes complete.		29 April
Policy implemented.	Transplant units, IAs and NHSBT	3 May
Update to Authority.		24 May
FAQs to be created for the website from the most common enquiries we receive in the first month.	(Provisionally to go to TWG)	22 June
Review of the process after 3 months.	Transplant units, IAs and NHSBT	29 July
Continue to support transplant units, IAs and surgeons.	Transplant units, IAs and NHSBT	Ongoing

Authority paper

Date	22 March 2011	Paper Reference	HTA (14/11)
Agenda item	8	Author	Caroline Browne

Post mortem tissue retention in Home Office cases

Background

1. There are three separate legislative frameworks that impact on the removal, storage and use of human tissue in relation to Home Office (forensic) post-mortem examinations: sections 19 and 20 of the Coroners Act 1988¹ and Coroners Rules 1984, the Police and Criminal Evidence Act 1984 (PACE) and the Human Tissue Act 2004 (HT Act).
2. Notwithstanding the complexity of the legislation and the different interests of the Coroner, the Police and the Judiciary in these cases, the starting point for every post-mortem examination is the Coroner's responsibility to determine the cause of death. Coroners are reliant on Pathologists to provide them with information about tissue retention in order that they can fulfill their statutory obligations under Coroners legislation.
3. To help the Police, Pathologists and Coroners find their way through the various statutory requirements, the Home Office produced a very helpful but weighty document entitled *Legal issue relating to forensic pathology and tissue retention* in 2007 (currently under review), to which the HTA contributed. This document has informed the advice that the HTA has provided to stakeholders, and has helped ensure a level of consistency. However, in recent months, concerns raised by Andrew Reid, HM Coroner for Inner North London, about the practices of the Forensic Pathology Services (FPS) in Oxford have brought one particular issue to the fore. Andrew's experience with FPS suggests that some Home Office Pathologists are failing to provide adequate information about tissue retention, which means that the Coroner is not able to comply fully with the requirements of the Coroners Rules.

¹Sections 19 and 20 of the Coroners Act 1988 will be superseded by s14 of the Coroners and Justice Act 2009; however, for the purposes of this paper, reference are to the 1988 legislation.

4. Although this may be seen primarily as an issue between Home Office Pathologists and Coroners, the HTA's regulatory remit over all post-mortem examinations means that we have a duty to ensure that appropriate systems of traceability and disposal are in place. This paper gives a brief and simplified overview of the legislative requirements as context and makes recommendations on how this problem may be addressed.

Statutory framework relating to forensic post mortem examinations

5. Over 95% of post-mortem examinations in England, Wales and Northern Ireland are requested and authorised by a Coroner, including those where the Police have an interest, and are therefore conducted by Home Office Pathologists. In relation to Home Office cases, estimated to number around 3,000 a year, there is sometimes uncertainty amongst the professionals involved about who has authority over tissue retained – the Police or the Coroner – and how the Coroners Rules apply. This may be exacerbated by exemptions under Section 39 of the HT Act in relation to activities undertaken for police purposes.

Coroners Act 1988 and Coroners Rules 1984 (as amended in 2005)

6. Home Office post-mortem examinations are conducted at the request and direction of the Coroner under section 20 of the Coroners Act 1988 and rule 5 of the Coroners Rules. As with any post mortem authorised by the Coroner, the Pathologist must inform the Coroner in writing that material that has a bearing on the cause of death has been retained, and the Coroner must, in turn, set a retention period that must not extend beyond the time the case is concluded by Inquest. The Coroner also has obligations under the Coroners Rules to inform the next of kin of the disposal options for the tissue when the case is concluded. This means that, for each post mortem conducted under their authority, the Coroner should have received from the Pathologist a list of tissue samples retained, they should have authorised the retention of these and specified the period for which they should be kept, and they should have notified the next of kin of the tissue that has been retained and explained disposal options. As mentioned earlier, Coroners are reliant on Pathologists to provide them with the information about tissue retention, in order that they can fulfill their statutory obligations under Coroners legislation.

Police and Criminal Evidence Act 1984

7. Police are present at forensic post mortems as 'properly interested persons'. On occasion, additional material will be seized by the police under PACE, over and above that which is retained for the Coroner's purposes. This material is required by the Police as part of a criminal investigation - the tissue samples are items of evidence and are subject to strict police requirements. Material seized by the Police for determining the criminal liability of a person is not subject to the

Coroner's authority. Occasionally, tissue will be retained for the Coroner's purposes (i.e. to determine the cause of death) as well as for police purposes (i.e. for the detection of a crime or the conduct of a prosecution). The Home Office has taken the position that, in Home Office cases, all material – including any taken by the Pathologist specifically for the purposes of the Coroner to help in determining the cause of death – is seized under PACE and is therefore subject to police exhibit management processes, including disposal. This is in an attempt to simplify processes. However, the system has not been rolled out across the country and the Home Office recognizes that it is a matter for the Police and Coroners to agree the approach to be adopted locally in their area.

Human Tissue Act 2004

8. Section 11 of part 1 of the HT Act exempts Coroners' post-mortem examinations from the consent requirements. In addition, section 39 of part 2 of the HT Act contains exemptions from the requirements of the HT Act for criminal justice purposes. Specifically, apart from the post-mortem examination itself, which must take place on licensed premises, the licensing requirements of the HT Act relating to removal and storage of tissue, do not apply, neither does anything within the remit of the HTA as set out in section 14. So removal of tissue from a deceased person by a Home Office Pathologist for criminal justice purposes, and the subsequent storage of that material, is subject to the exemptions under section 39.

Issues of concern

9. Of the 3,000 forensic post mortem examinations that take place every year, it is estimated that only around 800 result in murder trials. In the majority of cases, investigations show that the death is not suspicious and the Police should cease to be interested. However, from the correspondence shared with the HTA by Andrew Reid, the FPS seems to take the view that police powers of seizure continue even when the death is determined not to be suspicious, which means that the tissue remains outside the coronial system. In addition, FPS considers that tissue should not be disposed of until the Home Office Pathologist and the Senior Investigating Office have given permission for this to happen, which may extend beyond the retention period authorised by the Coroner. It is possible that this is the approach being taken by other forensic pathology services as well as by individual Home Office Pathologists.
10. As all Home Office post-mortem examinations are conducted under the authority of the Coroner, material that has a bearing on the cause of death is subject to the requirements of Coroners legislation; any other tissue retention is ancillary to the primary purpose which is for the Home Office Pathologist to determine for the Police and the Coroner the cause of death. If Home Office Pathologists don't acknowledge their responsibility to the Coroner, there is a risk to the HTA that

licensed establishments will end up storing tissue inappropriately and without consent when cases don't proceed to court.

11. There may also be a perception by some in the sector that the exemptions in section 39 of the HT Act apply universally, conflating the requirements of the HT Act and the Coroners Rules.

Recommendations

12. The issues discussed in this paper are not insurmountable. However, to resolve them, all parties will need a shared understanding of statutory requirements and to be clear about their obligations under each piece of legislation. It is proposed that, in collaboration with the Histopathology Working Group (which includes a Home Office Pathologist and Coroners), the following actions are taken:

- Production of a model tissue retention form for use by Home Office Pathologists
- Development of a model communication flowchart for Home Office post-mortem examinations, showing the responsibilities of each party
- Circulation of an HTA/Home Office jointly-branded letter to all Home Office Pathologists and forensic pathology laboratories clarifying the legal status of tissue samples.

13. The Authority is asked to approve these recommendations in order that work can begin early in the new business year.

Authority paper

Date	22 March 2011	Paper reference	HTA (15/11)
Agenda item	9	Author	Allan Marriott Smith Sue Martin

HTA Strategic Plan 2011–14 and Budget and Strategic Performance Review 2011/12

Purpose of paper

1. To provide the Authority with a near-final draft of the Strategic Plan for 2011–14 and to give the Authority sight of the budget and strategic performance review for 2011/12, thus providing assurance that plans are in place to deliver year one of the strategic plan.

Background

2. At its away-day in September 2010, the Authority considered the changes and developments of strategic importance in the external and internal environments since the last plan was published in April 2010, and in particular the challenges raised by the review of arm's length bodies (ALBs).
3. As a result of this activity, the Executive produced a draft Strategic Plan for the period 2011–2014, which Members discussed at the November Authority meeting.
4. Subsequently, further work has been undertaken to develop budgets and key performance indicators for 2011/12.

Action

5. The Authority is asked to:
 - approve the strategic plan for publication on the HTA website
 - note the efficiency plan
 - approve the outline budget for 2011/12

- note the content of the proposed structure of the Strategic Performance Review for 2011/12.

Strategic Plan 2011–2014

6. The Strategic Plan 2011-2014 is attached at Annex A.
7. The plan will be published on the HTA website at the beginning of the next business year.

Efficiency plan

8. The efficiency plan, which supports the business plan, is attached at Annex B. It describes the efficiencies we have made, and our plans to identify and prepare to make further efficiencies for 2012/13.
9. The Audit Committee has reviewed and is content with the plan.

Outline Budget 2011/12

10. During late 2010 and early 2011, the Executive undertook a detailed planning exercise to translate the strategic aims and high level objectives into a set of detailed business activities and objectives for 2011/12. The full detail will eventually translate into the performance development plans of individual staff members. In this way there is a clear link between the strategic aims and what each Directorate, team and individual contributes towards delivering the HTA strategic plan.
11. As part of this planning exercise, the Executive has estimated the staff time associated with the delivery of the plan. The staff costs of delivering each of the strategic aims have been calculated and other direct costs associated with specific pieces of work relating to individual aims have been identified.
12. The plan includes a high level budget. Further details are at Annex C, alongside the HTA's expected spend in 2010/11. There is still some uncertainty about licence fee income and expenditure in some categories so proposing a budget with a small surplus at this stage provides some flexibility.
13. The budget does not yet include details of funding and costs for the Organ Donation Directive. We have indicated to the Department of Health that revenue implementation costs will be approximately £100k in 2011/12 and expect notification of the additional Grant-in-aid in due course. We will then allocate the corresponding budget.

Strategic Performance Review 2011/12

14. From the detailed plan, the Executive has identified a series of key performance indicators (KPIs) (which will be monitored by the Authority each month in the Strategic Performance Review) and performance indicators (PIs) (which will be monitored by the Senior Management Team (SMT) each month). The KPIs will provide the Authority and Department of Health with high-level assurance that the strategic plan is being delivered, while the PIs provide SMT with assurance about the operational health of the business. The proposed KPIs for 2011/12 are shown on pages 12 and 13 of the Strategic Plan.



Human Tissue Authority

Strategic Plan 2011/12 – 2013/14

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Introduction

From Diana Warwick, Chair of the Human Tissue Authority

The landscape in which the Human Tissue Authority (HTA) operates has changed considerably since the last three year strategic plan was published a year ago and is now fundamentally different in two important ways.

The Spending Review published in October 2010 and the subsequent cuts imposed in public spending affect every part of the public service. In the last year, the HTA has made great progress in reducing costs and improving efficiency in its operations. Fees for 2011/12 have been set to reduce the HTA's income by 14 per cent, reducing the financial cost to licensed establishments, and providing better value for money. There is yet more to do over the coming years. This reduction goes beyond that required by the Department of Health and will be achieved without any reduction in the quality of what we do.

Second, with the publication of the review of arm's length bodies (ALBs) in July 2010, the Government recognised the continuing importance, sensitivity and quality of our work, but made the case for our functions to be transferred to other bodies, with an indicative date of April 2013 to achieve this. My concern, and that of the Authority, is to ensure that the functions for which we are responsible are protected so that the public and professionals can continue to have confidence that human tissue and cells are used safely and ethically and with proper consent. In January 2011 the Authority endorsed the view that the best way to achieve this goal is for the HTA's functions to be kept together as a single entity.

There are a number of principles which will guide us over the next three years as we undertake the transition to any new structural arrangements.

Protecting the excellent achievements of the HTA since it was formed should be of paramount concern in the transition to new arrangements; this means continuing to excel at the things we do well and continuing to find ways of doing things better.

The HTA must work with the Department of Health and the Government to ensure that the best possible structural arrangements are adopted to ensure that these achievements continue.

The people who make up the HTA team are critical to ensuring that we make this transition successfully and we will, therefore, continue to look after the interests of our people in the short and longer term; recognising their concerns; reducing uncertainty wherever we can; and keeping them fully informed so that we retain their commitment and expertise.

This will also be an exciting time for the HTA. In March 2011 we were chosen to be the competent authority for England and Wales for the European Union Organ Directive and will take the lead on developing a regulatory framework and implementing the Directive into legislation by August 2012.

This is an ambitious plan which will be challenging to fulfil, but I am certain that by continuing to work closely with the Department for Health, other regulators, and especially those we regulate, we will continue to deliver a trusted and highly effective service.

What we do – our remit

The HTA was established under the Human Tissue Act 2004 (HT Act) to regulate activities concerning the removal, storage, use and disposal of human tissue. Our role is to support public confidence by ensuring that their wishes will be respected and that bodies and tissue are treated ethically and safely. The HTA is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health.

We have several statutory functions. One is to inform the public, professionals and the Secretary of State for Health about issues within our remit. We meet this requirement for professionals by providing guidance, including codes of practice, to support good practice; and for the public by providing information to help them make informed decisions.

Another statutory function is to regulate licensing organisations that store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We license more than 850 organisations and publish standards that licensed establishments must meet: on consent; governance and quality systems; premises; facilities and equipment; and disposal. We also inspect organisations to check that they maintain good standards and follow appropriate procedures. Organisations we consider to be of the highest risk are among the first to be inspected.

As well as licensing under the HT Act, which covers England, Wales and Northern Ireland, the HTA is the Competent Authority in the UK responsible for ensuring the safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD). The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q&S Regulations) brought the EUTCD into force in the UK, including Scotland.

A third statutory function is the regulation, through an independent assessment process, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. The HTA also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

What we do – our remit

The HTA also oversees the consent requirements of the HT Act for deceased organ donation.

The Authority (the HTA's non-executive board) comprises a Chair and Members who are appointed by the Secretary of State for Health. Its primary role is to ensure that the HTA's statutory responsibilities are met. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an Executive who are responsible for the discharge of these responsibilities on a day-to-day basis.

How we do it – our strategic aims and high level business objectives

With the interests of both the public and those we regulate at the centre of our work, our overall strategic goal is to maintain confidence in the removal, storage and use of human tissue by ensuring that these activities are undertaken safely and ethically, in particular with proper consent. Public and professional confidence in our regulation has taken time to develop and maintain. It must be protected both now and following the transition to any new structural arrangements which result from the arm's-length body review.

Delivering this strategic plan during a period of change and uncertainty will depend greatly on our ability to be an organisation which has internal flexibility and manages resources efficiently and effectively.

We will reach our goal by fulfilling four strategic aims:

Strategic Aim One

To improve continuously the efficiency and effectiveness of our regulatory activity, and our advice and guidance

High level objectives 2011/12:

- a. To fulfil the HTA's statutory remit
- b. To share knowledge and experience gained from regulation and to help licensed establishments better meet HTA standards of quality
- c. To work internally, and with other regulators and the organisations we licence, to streamline and improve regulatory processes and practices.

Strategic Aim Two

To ensure appropriate and effective relationships with other organisations in our changing operational environment

High level objectives 2011/12:

- a. To maintain confidence in the regulation of the removal, storage and use of human tissue amongst professionals and the public
- b. To manage the reputation of the HTA effectively

- c. To engage stakeholders to inform regulatory and organ donation policy and processes
- d. To work with Government and other relevant organisations to ensure, that in any changes resulting from the arm's length body review, human tissue continues to be removed, stored and used safely and ethically.

Strategic Aim Three

To have a motivated and dedicated team equipped to do the job in a challenging transitional period

High level objectives 2011/12:

- a. To maintain an environment and culture that retains staff and upholds the HTA's standards and values
- b. To lead, motivate, involve and inform colleagues to deliver excellent work and to attract and retain the right people with the right skills
- c. To support delivery through high quality learning and development

Strategic Aim Four

To ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the tax payer

High level objectives 2011/12:

- a. To maintain proper governance and management arrangements during the period of transition
 - b. To achieve a step change in efficiency by reviewing systems, processes and procedures
 - c. To ensure the continued financial viability of the HTA.
-

How we monitor performance

Budget 2011/12

The Authority relies on an executive staff to deliver the strategic plan on a day-to-day basis. To achieve this, the Authority agrees a high level budget for the coming year and the executive develops detailed business plans which set out how it intends to deliver our objectives within this budget. The high level budget for 2011/12 is shown below.

Income	£000s
Department of Health funding	953
Licence fees	4,028
Other income	101
Total income	5,082
Expenditure	
<i>Operating costs, of which</i>	
Staff costs	2,979
Other operating costs	1,488
Total operating costs	4,467
Capital charges	550
Total revenue expenditure	5,017
Contingency	65

Costs associated with delivering strategic aims in 2011/12

The HTA has estimated the cost of delivering the strategic plan. Where staff time and costs can be associated with the delivery of specific areas of work, these have been allocated to strategic aims. Expenditure that supports the delivery of all aims is not allocated.

	Staff costs £000s	Other costs £000s	Total costs £000s
Strategic aim 1	1,270	10	1,280
Strategic aim 2	583	24	607
Strategic aim 3	315		315
Strategic aim 4	480		480
Unallocated	190	2,145	2,335
Total expenditure	2,838	2,179	5,017

Performance review

While the Executive implements and monitors delivery of the business plans, there are a number of mechanisms in place by which the Authority steers and reviews performance.

Authority meetings, which are held every two months, are the main means by which we set the direction on issues of strategic importance that emerge over the course of the year. They also provide the opportunity to assess the performance of the HTA. This is achieved through review of management information and more detailed reports on progress against elements of the strategic plan.

Each month, whether the Authority meets or not, it receives two key documents: the strategic performance review and the financial report.

Strategic performance review

This report provides a progress report against a set of key performance indicators (KPIs) which collectively give an indication of the health of the business. The Authority monitors progress using a traffic light system, whereby each indicator is assessed as red, amber or green. We receive more detailed briefing on remedial action being taken on objectives where the traffic light is showing either red or amber. The strategic performance review framework, including KPIs for 2011/12, is shown on pages 12 and 13.

Financial report

This report provides the Authority with assurances on the management of financial resources. The report provides commentary on the overall financial position, income and expenditure variances, forecast outturns and financial risks.

Both of these documents are published on the HTA website.

Managing risk

The HTA has in place arrangements for the identification, management and monitoring of risk. Day-to-day responsibility for the management of strategic and operational risk is delegated to the Executive but is monitored by the Authority's Audit Committee.

Efficiency plans

This strategic plan includes an objective to achieve a step change in efficiency by reviewing systems, processes and procedures. To ensure this is realised, the Authority has in place efficiency plans which set out in more detail the action being taken. Central to the efficiency plans for 2011/12 are a fundamental review of regulatory and business support processes and the further exploration of any savings that can be made from a move to shared services.

STRATEGIC PERFORMANCE REVIEW FRAMEWORK 2011-12

Unique ref	Strategic Aim Ref	Directorate Owner	Corporate Business Objectives	Indicator type	Performance indicators
1. To continuously improve the efficiency and effectiveness of our regulatory activity, and our advice and guidance					
a) To fulfil the HTA's statutory remit					
b) To share knowledge and experience gained from regulation and to help licensed establishments better meet HTA standards of quality					
c) To work internally and with other regulators and the organisations we licence to streamline and improve regulatory processes and practices					
KPI 1.1	a	Regs	To license five sectors under the Human Tissue Act	Measure	At least 90% of completed new licence applications are processed within 20 working days of completion of the site visit inspection
KPI 1.2	a	Regs		Measure	At least 90% of variations to licences are processed within 20 working days of receipt
KPI 1.3	a	Regs		Measure	At least 90% of new licence applications to include a site visit inspection
KPI 1.4	a	Regs	To inspect Human Application establishments regulated under the Q&S Regs	Measure	At least 180 site visit inspections to take place during the business year (Reported quarterly). Will be replaced with inspection profile.
KPI 1.5	a	Regs		Measure	At least 90% of inspection reports published within 12 weeks of the end of the inspection
KPI 1.6	a	Regs		Measure	At least 90% of respondents rate the overall inspection process as either 'good' or 'excellent'
KPI 1.7	a	Regs		Measure	At least 90% of Corrective and Preventative Action (CAPA) plans are completed within agreed timescales
KPI 1.8	a	Regs	To provide advice and guidance to licensed establishments	Measure	At least 95% of enquiries from licensed establishments are answered within 10 working days of receipt
KPI 1.9	a	Regs	To undertake activity to implement the requirements of the Organ Donation Directive	Milestone	Project Red-Amber-Green (RAG) status remains Green during project implementation stage.
KPI 1.10	b	Regs	To inspect PM, Anatomy, Reseach and Public Display establishments regulated under the HT Act	Measure	At least 180 site visit inspections to take place during the business year (Reported quarterly). Will be replaced with inspection profile.
KPI 1.11	b	Regs		Measure	At least 90% of inspection reports published within 12 weeks of the end of the inspection
KPI 1.12	b	Regs		Measure	At least 90% of respondents rate the overall inspection process as either 'good' or 'excellent'
KPI 1.13	b	Regs		Measure	At least 90% of Corrective and Preventative Action (CAPA) plans are completed within agreed timescales
KPI 1.14	c	Strat	To manage the work stream associated with assessing non genetically or emotionally related directed donations	Milestone	Assessment process in place for these cases by end of Q3
KPI 1.15	c	Strat		Milestone	Guidance for transplant teams revised, published and has the support of the transplant community by end Q4

STRATEGIC PERFORMANCE REVIEW FRAMEWORK 2011-12

Unique ref	Strategic Aim Ref	Directorate Owner	Corporate Business Objectives	Indicator type	Performance indicators
2. To ensure appropriate and effective relationships with other organisations in the changing environment in which we operate a) To maintain confidence in the regulation of the removal, storage and use human tissue amongst professionals and the public b) To manage the reputation of the HTA effectively c) To engage stakeholders to inform regulatory and organ donation policy and processes d) To work with Government and other relevant organisations to ensure, that in any changes resulting from the arm's length body review, human tissue continues to be removed, stored and used safely and ethically					
KPI 2.1	a,b,c	Comms	To monitor confidence in HTA regulation among the post-mortem sector.	Measure	Gauge level of confidence in comparison with the previous survey (76% had great deal or fair amount of confidence in the HTA as a regulator)
3. To have a motivated and dedicated team equipped to do the job in a challenging transitional period a) To maintain an environment and culture that retains staff and upholds the HTA's standards and values b) To lead, motivate, involve and inform colleagues to deliver excellent work and to attract and retain the right people with the right skills c) To support delivery through high quality learning and development					
KPI 3.1	a,b	CEO	To manage HTA recruitment	Measure	Target 0% vacancy rate for business critical posts and minimum requirement non-business critical posts
KPI 3.2	a,b	CEO	To implement targeted retention initiatives	Measure	Attrition rate and exit interview analysis of reasons for leaving.
4. To ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the tax payer a) To maintain proper governance and management arrangements during the period of transition b) To achieve a step change in efficiency by reviewing systems, processes and procedures c) To ensure the continued financial viability of the HTA					
KPI 4.1	a	Res	To develop and deliver the ALB review transition project.	Measure	Project Red-Amber-Green (RAG) status remains Green during project implementation stage. Timing to be agreed.
KPI 4.2	b	Res	To develop and deliver the efficiency plan	Measure	Efficiency of at least 10% made on Grant-in-aid funded expenditure
KPI 4.3	c	Res	To set appropriate fee levels for 2012/13	Measure	Fees to be no more than 2011/12 levels or to generate £4.5m in revenue

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The Human Tissue Authority's efficiency plans

Introduction

An aim of the HTA's strategic plan is to "ensure the HTA is effectively governed and managed efficiently, providing value for money for licensed establishments and the tax payer". A high level objective is to "achieve a step change in efficiency by reviewing systems, processes and procedures".

These plans build on work in previous years which has led to 14% efficiency savings reflected in the 2011/12 budget. Grant-in-aid has reduced by 10% and the HTA has made efficiencies enabling us to manage with 14% less income from licence fee, enabling us to reduce licence fees.

This efficiency plan summarises the actions we have taken and how we plan to review our processes to ensure greater efficiency in the coming years. Grant-in-aid will continue to reduce (by a total of 33% over three years from the 2010/11 level) and it is important to keep licence fees as low as possible, recognising that licensed establishments live in challenging financial times. The HTA will build on experience to streamline regulatory and other processes, managing with reduced Grant-in-aid and passing savings onto licensed establishments.

Efficiencies in place for 2011/12

Regulation

The Hampton Implementation review Report in July 2009 rated the HTA highly on provision of advice and guidance and minimisation of inspection and data collection burdens. MORI research shows that around half of our stakeholders think our performance has improved in the last 3 years and 58% would be advocates for the HTA.

The HTA has continued to look for ways to streamline regulation and the processes, making efficiency savings. In 2010 we analysed how we are spending our time and reviewed processes. We streamlined the way we assess new applications, standardised the preparation, conduct and reporting of inspections and clarified and made more effective the way we manage areas for improvement at licensed establishments. This has led to a reduction in staff time and enabled us to pass on savings to licence fee payers.

During 2010 the HTA started to make joint inspection visits with the Medicines and Healthcare products Regulatory Agency. These reduce the burden on the establishments being visited and in time should reduce the amount of resource each organisation spends on inspection.

The HTA has developed updated risk assessment tools to better focus resource on high-risk groups and reduce inspection of establishments with good compliance.

A CRM system has been developed to replace several custom built systems that were developed some time ago and are costly to manage. CRM also streamlines workflow and will be more efficient in terms of the quality and ease of data manipulation, as well as providing a better service for external users. The new online submission system, launched for 2010/11, provides enhanced support to manage the transplant approval process more efficiently. CRM uses standard software and future developments will also be more cost efficient than developments on the old systems.

The HTA also develops and reviews guidance documents and codes of practice regularly to ensure they are proportionate and provide helpful information to improve compliance and encourage self reliance by establishments. Codes are published in an interactive, accessible online format to encourage and facilitate use. The HTA also analyses enquiries received to inform guidance and better provide for our stakeholders.

The Communications Team has reduced by 33% since 2010, with more efficient horizon scanning and media monitoring, targeted intervention and a different role of supporting regulation staff in communications rather than undertaking these themselves.

Other Business Support Services efficiencies

The HTA has critically assessed the most efficient way of delivering functions, such as Finance, IT and HR, and the scope for outsourcing. We manage with a flexible and adaptable small core of staff, who have reduced in number since 2010 and cover a wide range of duties to meet the HTA's needs. There is a need for a minimum number of staff to support the business, regardless of whether they are managing shared or outsourced functions or delivering directly and regardless of the size of the organisation.

Financial services and management information are provided by a team of two staff, who also support governance at the HTA and other services. They co-ordinate risk management, support the Audit Committee, oversee enquiries and complaints, review the licence fee rates annually, maintain finance policies and guidance, process financial transactions and realise licence fee income. This arrangement is efficient in a small organisation such as the HTA. It ensures that appropriate strategic financial and business advice is provided to the Senior Management Team and allows the HTA to respond rapidly and flexibly to business need. Over 2010/11 the staff have taken on more duties around licence fees and general support to the HTA.

IT support is outsourced and efficiencies have been made by consolidating support services and reducing the number of separate contracts. The HTA has a Head of Business Technology who manages IT contracts and provides strategic advice. In addition he manages accommodation, facilities, information governance and other office services, as well as acting as project manager for the office relocation. Over 2010/11 the two support staff in this area decreased by 75% to 0.5.

HR services are provided by one member of staff, with payroll outsourced. She provides recruitment advice and management and advice and support on all HR matters, including grievance and disciplinary situations and the maintenance of individual personnel records. This meets the needs of the HTA, providing a flexible solution to give strategic support to the Senior Management Team and delivering operational work cost effectively. Resource on HR has decreased by 50% since 2010/11.

The HTA shares the services of other organisations (eg reception, cleaning, post, security, conference and refreshment facilities provided through the Department for Business Innovation and Skills and media monitoring through the Medicines and Healthcare products Regulatory Agency) and intends to continue to review scope for further shared services, with other occupiers of our building and in line with the planned transfer of functions. As a small organisation, only a small number of staff are involved in transactional services that can be shared without harming the delivery of the HTA's purpose and independence, and it is a small part of those people's jobs. Therefore savings from sharing services are difficult to realise. Where it is not more efficient to share services, the HTA works closely with other organisations to share expertise and spread good practice. For example, the HTA uses the procurement expertise of the Department of Health and other ALBs.

All spend has been critically examined in 2010 and we have reduced the amount of venue hire, ceased to insure, ended contracts for legal and HR advice services, sourced cheaper printing and other office services. We have also reduced our administrative support by 40% by creating a flexible "pool" of assistants and PAs.

The changes made in 2010 have allowed us to reduce licence fees by 14% for 2011/12 and manage with 10% less Grant-in-aid. Efficiencies realised in previous years have been passed back to establishments who have paid more fees than we have needed as a rebate.

As well as some cash savings, efficiencies allow us to do more for the same investment. Staff time released by new processes and technologies is used to improve quality, engage with stakeholders and keep abreast of new developments in legislation and research.

Estates

In December 2010, following an acquisition and refurbishment managed by DH, the HTA offices moved to 151 Buckingham Palace Road. This building is held as Government estate through the Department for Business Innovation and Skills and DH's long standing plans to move ALBs here is part of their Property Asset Management Plan. The HTA plans to remain at 151 BPR until its functions are transferred to other regulators and it ceases to exist.

The HTA occupies 645 square meters on part of the second floor, the space remaining following design to meet the other occupant's needs. This is to accommodate the agreed staffing limit of 67 and leads to 9.6m per FTE

(compared to the Government's average target of 10). There is currently no scope to reduce this space.

The fit out and building services have been designed with efficiency in mind. BIS manage the building and the HTA adheres to their arrangements regarding energy consumption etc. HTA staff are informed about the need for efficiency in using facilities.

Procurement

The HTA works within the DH specified guidelines for efficient and central procurement. The HTA continues to manage contracts to review the need for goods and services, source this efficiently and plan for contract end dates. During 2010/11 two contracts were let using Buying Solutions Frameworks.

The HTA is mindful that it may not exist as an organisation after 2013 and is managing contracts accordingly. Termination arrangements are understood and appropriate action is being taken. Procurement likely to require DH approval is set out on DH's Annex B, although this is speculative until more detailed plans have been made.

Future efficiencies

The HTA has started discussions with the Business Shared Services Transition Programme and the Care Quality Commission, to determine when and how best services would move to a shared arrangement, starting with HR, Finance and Procurement. We also intend to move to shared internal audit services as soon as possible. It is unlikely that these arrangements will be cheaper for the HTA, but we are mindful of wider considerations.

From January 2011, we are starting our efficiency planning for 2012/13. We expect Grant-in-aid to reduce further and we want to keep licence fees as low as possible. The HTA will build on previous work and operate as a fit and healthy, efficient organisation.

The outline timetable is:

January-March 2011

Fundamental review of processes (regulatory and business support), but building on earlier work, of what do we need to do, what is the best way of doing it and what resources do we need

Outcome: Areas for change and what the change is identified, and the resource saving estimated

April-June 2011

Work through implications for making changes (developing processes, communicating/consulting, training, launching), implications for staffing and contracts and timing

Outcome: Agreed change plans

July 2011

Summarising and agreement

Outcome: Authority agreement to budget likely to be required after efficiency savings proposed, taking account of Grant-in-aid constraints, leading to setting licence fee rates

July 2011-March 2012

Implement process change and manage staffing, business planning and budget setting for 2012/13

Outcome: Clear understanding of new processes; staff required in place to manage within budget allocation

HTA

January 2011

	Notes	2011/12 Budget £000k	2010/11 Forecast outturn £000k	Variance £000k	Variance %
Income:					
DH Funding		953	1,059	(106)	(0.1)
Licence Fees	1	4,028	4,897	(869)	(0.2)
Other Income		101	101	0	0.0
Total Income		5,082	6,056	(974)	(0.2)
Expenditure summary					
Staff costs	2	2,979	3,117	(138)	(0.0)
Travel & subsistence		95	104	(9)	(0.1)
Training & recruitment	3	215	128	87	0.7
Conferences & Events		78	143	(65)	(0.5)
Post, stationery & printing		43	60	(17)	(0.3)
Other costs		37	49	(12)	(0.2)
I.T. & telecommunications	4	320	278	42	0.2
Legal & professional		158	169	(11)	(0.1)
Consultancy		15	55	(40)	(0.7)
Accommodation	5	527	679	(152)	(0.2)
Non cash costs		-	18	(18)	(1.0)
Total operating costs		4,467	4,800	(333)	(0.1)
Capital charges		550	606	(56)	(0.1)
Capital expenditure		-	-	-	-
Total Expenditure		5,017	5,406	(389)	(0.1)
Surplus/(Deficit) of income over expenditure	6	65	650	(585)	(0.9)

Notes:

- 1 Expected licence fee income for 2011/12 is based on assumptions about licensed activities.
- 2 Staff costs reflect the new organisational structure.
- 3 The proposed budget for recruitment includes provision for external recruitment of Regulation Managers and other key staff that was not required in 2010/11.
- 4 IT development costs are all shown here for 2011/12. In 2010/11 there was a capital budget.
- 5 Accommodation costs for 151 BPR are to be confirmed.
- 6 Surplus budget required because of uncertainty.

Authority paper

Date	22 March 2011	Paper Reference	HTA (16/11)
Agenda item	10	Author	Sara Coakley Shaun Griffin

The Communications Strategy 2011–2013

Purpose of the paper

1. This communications strategy supersedes the one presented to the Authority in May 2007. The Authority is asked to endorse the new strategy and support its implementation.

Introduction

2. This is an Authority-wide strategy which, building on the success of the last, shifts emphasis to bringing a stronger public focus to our communications activities, and supporting our objectives in relation to the arm's length bodies (ALB) review. Its implementation will involve the effort and cooperation of all staff and Authority Members.
3. This should be seen as a living document subject to regular review – in such an ever-changing environment, we will continue to be flexible to new developments. The Senior Management Team (SMT) will lead in supporting and advocating the roll out of these new objectives. Members will continue to receive regular reports on the delivery of the strategy.

Background

4. The strategy (presented in the Annex) supersedes the one agreed by the Authority in May 2007 and will run until 2013 or until the Arm's Length Bodies review dictates otherwise. It sets out a framework that reflects the HTA's strategic aims and aligns with the annual corporate business plan.

5. This strategy is significantly different from that agreed in May 2007. We have now become firmly embedded and influential in the regulatory landscape and have been recognised as having made solid achievements in the way we communicate, as evidenced by the Ipsos MORI poll in 2010, for example. We are now seeking to focus on communicating with the public – and in particular getting feedback from people affected by our regulation – in the same way we have successfully communicated with professionals. We will also focus on delivering our objectives in relation to the ALB review.
6. The proposals contained in the strategy have taken into account current staffing of four people in the Communications and Public Affairs Directorate, and the changing external environment. As we are delivering business as usual for our external stakeholders, the maintenance of key communication streams is just as important as the creation of new ones. Both of these factors are covered in this strategy, which also supersedes the media and internal communications strategies.

Recommendations

7. Members are asked to endorse the strategy and agree to:
 - the core messages
 - the four communications objectives
 - the high level action plans 1–7

Authority paper

Date	22 March 2011	Paper Reference	HTA (16/11) - Annex
Agenda item	10	Author	Shaun Griffin Sara Coakley

Communications strategy 2011 – 2013

The strategy

1. This strategy document describes a framework for communications activity for the next two years (2011–2013) or until the Arm's Length Bodies (ALB) review dictates. Building on the success of the last strategy we are now seeking to focus on communicating with the public – in particular in getting feedback – in the same way we have successfully communicated with professionals, and on delivering our objectives in relation to the ALB review. The strategy sets out key objectives and the actions needed to achieve them, which the Executive, with support from Authority Members, will take forward during that period. The Authority will receive regular updates which will include details of any changes to the action plans in response to the Authority's changing operating environment.
2. Whilst the strategy will be managed and facilitated by the Communications and Public Affairs Directorate, its delivery will require the input, support and cooperation of staff and Members. Our success in communicating effectively depends on all staff and Members being alert to communications issues and promotional opportunities, functioning as the eyes and ears of the Authority, and acting as ambassadors/spokespeople.

History and summary of achievements since last strategy

3. The focus of our last communications strategy of May 2007 was on increasing our profile and ensuring professionals both understood and had confidence in us as a regulator. There was also a considerable amount of focus around the proposal for a Regulatory Authority for Tissues and Embryos; it was a priority that our positive profile and reputation was increased in the media and with key

opinion formers, allowing the best of the HTA to be brought forward into the proposed successor organisation. The last communications strategy had three strategic objectives:

- increasing our profile to ensure our regulatory framework is understood and appreciated, and can be used as a model for other regulators
- working with the media to increase our profile and to ensure confidence in the systems we put in place
- supporting this work through improved internal communications and knowledge management

Achievements

4. The 2007 communications strategy has been implemented successfully:

- The HTA brand gives a consistent look and feel across all our publications and the website and reflects a professional image.
- Our website has been re-structured, and user-testing and evaluation show that it is useful, easy to navigate and informative. The professional survey conducted by Ipsos MORI in 2010 revealed that three quarters of respondents believe the homepage gives a clear overview of what can be found on the site.
- The qualitative survey revealed that the majority of stakeholders are happy to use electronic means to receive information and there was positive feedback about the quality of the e-newsletter and the HTA website.
- Increased stakeholder engagement and profile-raising has resulted in an increase in public and professional confidence between 2007 and 2010, as demonstrated by Ipsos MORI polls. Three years after the first survey, the findings show a five percentage point increase in the proportion of adults who have confidence in human tissue regulation – from 52% to 57%. In addition, professional confidence has risen to 86%.
- The HTA scores very highly (84%) on keeping its professional stakeholders informed, coming second out of seventeen when benchmarked against other public sector organisations in Ipsos MORI's data bank.
- Our Annual Review publication has been well received; and in the last few years its launch, combined with a public event, has raised our profile and enhanced our reputation as a regulator.
- In the regulated sectors, summary compliance reports show that standards have risen over time. The Communications and Public Affairs Directorate

has supported the formulation and dissemination of clear advice, guidance, education and training across all sectors.

- Our profile with journalists has increased and they are now more aware of what we do and approach us more often. We also have a positive public profile.
- Internal communications have developed significantly with information being shared via the staff newsletter, instant email alerts on significant issues, a dedicated information portal for staff (HTAik), a staff forum, and all staff meetings being the norm.

Challenges

5. We have faced, and continue to face, challenges in relation to the ALB review; our relationship with the post mortem sector; the potential impact of changing consent laws on our ability to regulate; and doing more with less. New challenges include communicating the requirements of the Organ Donation Directive. These challenges will be overcome through producing and delivering robust strategic communications plans.

Definition and scope of strategy

Aim

6. With the interests of the public and those we regulate at the centre of our work we aim to maintain confidence by ensuring that human tissue is used safely and ethically, and with proper consent. The focus of this strategy is to communicate with the public in the same way we have successfully communicated with professionals; and to deliver our objectives in relation to the ALB review.
7. In order to maintain confidence especially in such a shifting external environment we need to ensure that high quality, timely and accurate information is widely available to those we regulate and the public, and that we get feedback from people affected by our regulation.
8. This strategy sets out a new direction to engage proactively with the public as the end-user of our services to ensure we have their confidence. Current activities will not be lost and are woven into the new communications objectives. The ALB review and the passage of the Public Bodies Bill have had a big impact on the work of the Directorate with significant resources being shifted into this area. This is a time- and task-focused piece of work and is therefore recognised as a separate communications objective in its own right.

Core messages

9. If the Authority is to be sure that our work in maintaining confidence and expanding an understanding of what we do to the wider public is realised, then we must first be able consistently to describe what our work involves. This will also feed into helping us explain to professionals the benefits and importance of what we do, and will help inform Key Opinion Leaders and others about our interests in relation to the ALB review.
10. The following core messages describe the work of the Authority and represent the highest level key messages which the Authority will be seeking to communicate through this strategy.

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

11. The direction of travel is towards a more outcome-based approach to regulation – i.e. how it affects the end user – and our communications messages will better reflect this outcome-focus.
12. The Authority will take every reasonable opportunity over the lifetime of this strategy to communicate and reinforce these messages and will, of course, keep them under review to ensure they continue to communicate our objectives clearly and accurately to key audiences.
13. These core messages are headlines, which will be expanded upon when delivering the communications objectives. However, wherever we seek to explain our role, these core messages, the concepts they set out, and the language they use will be the starting point. By doing this, we will build an even more robust and consistent understanding of what we do and why we do it.

The HTA's strategic aims

14. The HTA's agreed strategic aims are listed below:

- Strategic aim one: to continuously improve the efficiency and effectiveness of our regulatory activity and our advice and guidance.
- Strategic aim two: to ensure appropriate and effective relationships with other organisations in the changing environment in which we operate.
- Strategic aim three: to have a motivated and dedicated team equipped to do the job.
- Strategic aim four: to ensure the HTA is effectively governed and is managed efficiently, providing value for money for licensed establishments and the taxpayer.

The communications objectives

15. This communications strategy proposes four high level objectives that reflect the HTA's agreed strategic aims set out above. The communications objectives are also mirrored in the annual corporate business plan. The range of activities which the Authority could undertake in order to deliver the stated aims of this strategy is considerable. In addition, our action plans will need to evolve to meet the changing environment within which we operate. To make the best use of our resources, the Authority must have clear strategic objectives to inform all communications activities. The core messages above and an understanding of the HTA's stakeholder base underpin these objectives.

16. These strategic objectives are comprehensive and measurable. We will need to keep them under regular review.

17. Finally, we must be able to respond to the changing environment rapidly, whilst ensuring we remain coherent and consistent with our messaging in the long-term.

18. The objectives proposed here have been discussed and agreed at the Communications Members' Group meeting on 25 January 2011 are:

- Building public confidence
- Engaging with professionals
- Influencing the ALB process to protect our functions
- Using internal communications to support staff

The toolkit

19. The Communications and Public Affairs Directorate has a strong knowledge of the business which will support the delivery of the strategy. To achieve many of the stated aims in this strategy we will use the standard toolkit below. Actions 1–7 listed with the objectives highlight ways in which we aim to achieve these, they are by no means definitive and in some cases we might use more or fewer tools, in order to complete a given task. However it is helpful to highlight the range of tools at our disposal.

Key tools
<p>Media</p> <ul style="list-style-type: none"> • Strong contacts with all lead health journalists • Strategic and thorough understanding of broadcast media • Considered first point of contact in areas of expertise • Strong ‘selling in’ skills • System for monitoring
<p>Public Affairs</p> <ul style="list-style-type: none"> • Strong understanding of how parliament works • A robust database of supporters • Identifying and utilising networking opportunities • Regular communiqués with parliamentarians
<p>Publications and website</p> <ul style="list-style-type: none"> • Good understanding of editorial style • Good system for updating pages • Strong set of case studies and key messages • Contacts and understanding of printing and design

Building public confidence

(Relates to strategic aims one, two and four)

When it comes to communications, familiarity breeds support

20. In their 2010 survey, Ipsos MORI found that the general public were not necessarily aware of us, by name but their confidence in ‘the system’ we regulate had increased. We also know that knowledge of regulation increases confidence to donate. In the long term, this may mean that, if the public is aware of our work they will be more willing to donate for different purposes, with positive healthcare outcomes. However with a more outcome-based shift in direction we need to target our work to the end user which we have not done previously.
21. We need to identify individuals affected by what we do and engage with them. For example, those who would stand to lose or gain the most because of our regulatory activities. We can then assess the most effective way to reach them – through education we can create awareness. In short, we need to put the same level of effort into communicating with the public as we have done with professionals since our inception, to ensure we understand their needs. This, in turn, can inform our approach to regulation.
22. Key to the success of this objective is for Members, the Senior Management Team (SMT) and all staff to collectively make the cultural shift to view ‘the public’ rather than ‘professionals’ as our primary end user. This should not be done at the expense of, or instead of, the good communications we currently have with professionals. With the support of the rest of the organisation in communicating with professionals, there will be more space and time to embrace a new direction of travel in reaching out to the public.
23. Actions 1–3 below details of how we would map and communicate with the public to achieve this objective.

Action	How	Measurable
1. Outreach to the general public. Most ‘public’ fall outside specific groups and we need to reach the majority to build confidence by increasing awareness	One proactive press release a month Build library of human interest stories for use across a multitude of areas e.g. the website, press releases, use as advocates, inform policy, the annual review etc.	Increased press coverage/exposure = increased awareness Increased numbers of case studies, increased story placement, increased numbers of positive comments.

2. Map public groups by conducting a gap analysis of current stakeholder database and expanding horizon to engage with new groups.	Consult 'warm' stakeholders, other ALB's, Members and staff.	An expanded, current and informative public groups database.
3. Engage with public groups – we need to open up new two-way channels of communication to maximise information delivery in both directions.	Develop programme for engagement including: informal networking, formal networking; seeking speaker slots, attend events, use internal communications to make staff cultural shift.	Monitor media for increased numbers of positive hits. Increased numbers of groups willing to help.

Engaging with professionals

(Relates to strategic aims one, two and four)

Good regulation supports good practice which in turn improves confidence

24. Ipsos MORI told us in 2010 that professional confidence in the HTA had increased significantly to 86% since 2007. This high level of confidence will only remain so if our engagement is continuous, relevant and regular. Whilst relations have improved with the post mortem sector we must continue to keep watch over our interactions with them.
25. We will need to conduct a desk-based gap analysis to, for example, identify any missing professional organisations/individuals. We need to recognise the way they work and to better understand the challenges they face in their jobs and identify where we are not currently meeting their needs.
26. We need to foster good relations with professionals and increase the number of ambassadors who can help us reach out to the public as well as influence the ALB process. We need to engage with them to help us formulate relevant and useful advice and guidance for their sectors. We need to get our core messages across, explain why we regulate and what this could mean for them i.e. sell the benefits to them being accredited/kite-marked by the HTA.
27. Actions 4–5 below details how we would map and communicate with professionals to achieve this objective.

Action	How	Measurable
4. Desk-based survey of current stakeholder map including gap analysis. We need to recognise the way they work, understand the challenges they face, identify where we're not meeting their needs.	Use current knowledge, draw on staff and their networks, meet and greet with other communications teams in KOL organisations.	Increased current and informative database. Increased numbers of professionals willing to help us.
5. Regular communiqués in order to keep two way communications warm especially in areas such as PM sector and the ALB review. Promoting the benefits of HTA 'kitemark'.	Use all the tools listed in toolkit above	Increased compliance.

Influencing the ALB process

(Relates to strategic aims one, two and four)

Be part of the solution not the problem

28. Influencing and informing, is mission critical at this juncture to protect our functions and keep them in one place. Influencing the outcome of the ALB review will ensure that our functions are kept together in a way that makes sense for the business. To achieve this we must engage with, and work in partnership with, key figures and other organisations.
29. It is imperative that we keep staff and stakeholders up to date with relevant, consistent and frequent messages. We need to ensure our two-way communication channels are fit for purpose in order to retain staff and ensure regulatory standards are met – the 'business as usual' message is a priority for the sectors we regulate. Managing change in these unsettling times needs to be handled in a sensitive and timely manner (this issue is also covered in the internal communications objective).
30. Action 6 below details how we are currently communicating with our audiences to achieve this objective.

Action	How	Measurable
6. Engage with key figures and organisations, if they are aware they can promote and defend us – no one can sell your business better than someone else. Also need to maintain confidence in business as usual during transition.	Asking Key Opinion Leaders to speak on our behalf. Work with other ALBs, engage with DH and keep staff informed throughout whole process.	Functions kept together. Compliance not affected through transition period.

Using internal communications to support staff

(Relates to strategic aim three)

An engaged and motivated workforce produces the best ambassadors

31. Our staff are key to our success: we need their buy in to maintain the business, to help deliver this communications strategy, and to manage big organisational change. Clearly relationships between staff and professionals and Key Opinion Leaders are crucial, and we will support the organisation to take more of a lead in communicating with these groups. As the new focus of this strategy is the public as the end-user of our regulation, we will need the support of the Executive in promoting a clear outcome focus to our activities.
32. In this ever changing environment we must engender and then maintain two-way trust, this will increase productivity and morale and will help support organisational change. SMT and Members will communicate a clear vision to support this.
33. Action 7 below details how we are currently communicating with and plan to communicate with our staff to achieve this objective.

Action	How	Measurable
7. Communicate clear managerial vision especially on change issues to ensure staff 'buy in' to manage big organisational change.	Openness and timeliness of information sharing, including good news stories/endorsements. Reward and recognition.	Compliance remains on target. Sickness and staff attrition rates not increased.

Authority paper

Date	22 March 2011	Paper Reference	HTA (17/11)
Agenda item	11	Author	Allan Marriott-Smith

Strategic Performance Review – February 2011

Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during January. 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 HTA's strategic aims are being delivered.
3. The Authority has agreed upon the following approach in 2010/11:
 - More detailed reporting where a KPI is showing red or amber, including an account of what action is being undertaken to return the indicator to green.
 - Improved narrative supporting KPIs will be enhanced to better explain the messages behind the indicators, in particular whether they raise issues of strategic concern.
 - Improved ad hoc briefing throughout the year focussing in greater detail on performance issues in relation to each of the five strategic aims.

Progress in February 2011

Compliance and Enforcement Policy and Compliance

4. All KPI's on target.

Communications and Public Affairs Transplants

5. All KPI's on target.

Resources

6. All KPI's on target.

CEO

7. The KPI (4.1) for **attrition rate** on the twelve month rolling basis over the business year has been judged to be red as the attrition rate is 33%, relative to the target rate of 18%. The calculation is for 1 March 2010 to 28 February 2011 with a start headcount of 54, end headcount 43 with 16 leavers in this twelve month period. (Previous three figures were: year to end January 37%, year to end December - 35%, year to end November – 35%). In addition the headcount over the month remained static at 43.
8. The Authority has previously noted the action being taken to improve staff retention. The KPIs proposed to monitor this situation in 2011/12 are set out in paper HTA (15/11).

Strategic Performance Review February 2011																			
Unique ref	Strategic Aim Ref	Owner	Business Plan Objective	KPI type	KPI	A	M	J	J	A	S	O	N	D	Delivery Update			Comments	
1. Continuously improve the quality of our regulatory activity and our advice and guidance															J	F	M		
(a) To fulfil the HTA's statutory remit in relation to all licensable activity																			
(b) To fulfil the HTA's statutory remit in relation to advice and guidance																			
(c) To ensure the HTA meets the duties of the Competent Authority for Tissue and Cells																			
(d) To fulfil the HTA's statutory remit in relation to consent and organ donation																			
KPI 1.1	a/b	Regs	To continuously improve regulatory compliance through proportionate, consistent, transparent and risk based regulatory activity.	Measures	Number of licensing decisions (measured quarterly).			68			79			48					
					Number of representations and appeals (measured quarterly).			0			1			0					
					Proportion of representations and appeals upheld (measured quarterly).			0			1			0					
KPI 1.2	a/b	Regs	To continuously improve regulatory compliance through proportionate, consistent, transparent and risk based regulatory activity.	Measure/ Milestone	Proportion of all additional licensing conditions in breach over the course of the business year (measured monthly). Target to halve proportion over the business year.														
					PM Sector	0% (0/17)	17% (2/12)	0% (0/8)	50% (7/14)	0% (0/15)	0% (0/8)	0% (0/6)	0% (0/14)	0% (0/0)	0% (0/9)	0% (0/0)			
					HA Sector	12% (4/33)	0% (0/7)	13% (4/31)	17% (5/29)	13% (2/16)	38% (5/13)	36% (8/22)	0% (0/11)	40% (4/10)	13% (2/15)	0% (0/5)		(Jan) - There is one establishment with two open conditions on their licence. The establishment provided the compliance information too late to make the assessment within the required time period.	
					Other sectors	0% (0/2)	0% (0/6)	0% (0/0)	0% (0/0)	0% (0/6)	0% (0/0)	0% (0/1)	0% (0/0)	0% (0/2)	0% (0/0)	0% (0/0)			
					All sectors	8% (4/52)	8% (2/25)	10% (4/39)	33% (12/43)	5% (2/37)	24% (5/21)	28% (8/29)	0% (0/25)	33% (4/12)	8% (2/24)	0% (0/5)			
KPI 1.3	a/b	Regs	To undertake a risk based and targeted site visit inspection programme: to include all remaining post mortem sector establishments.	Measure	95% of planned PM sector establishment inspections completed by Q4 (actual proportion measured monthly).	G	A	G	G	G	G	G	G	G	G	G			
					Expected cumulative profile.	8	13	15	17	23	33	42	53	54	60	74	76		Reprofiled: 07/06/10
					Outturn profile	8	12	15	17	23	34	44	51	53	61	70			
KPI 1.4	a/b	Regs	To fulfil the HTA's statutory remit to inspect human application establishments.	Measure	95% of planned HA sector establishment inspections completed by Q4 (actual proportion measured monthly).	G	A	G	G	G	G	A	G	A	A	G			(Oct) The reason for the amber status is described in the covering Authority paper. (Dec) The reasons for the amber assessment are described in the Authority paper.
					Expected cumulative profile.	3	12	24	38	42	46	50	57	61	68	75	91		Reprofiled in July for period August to March.
					Outturn profile	4	9	25	39	42	44	47	54	57	64	71			
KPI 1.5	d	Pol	To manage living organ donation approvals to agreed quality standards.	Measures	Proportion of panel cases turned around within 10 working days (measured monthly). Target rate 97%.	100%	80%	100%	100%	100%	100%	100%	100%	100%	100%	100%			
					Proportion of non-panel cases turned around within 5 working days (measured monthly). Target rate 97%.	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%			

Strategic Performance Review February 2011																		
Unique ref	Strategic Aim Ref	Owner	Business Plan Objective	KPI type	KPI	Delivery Update												
2. Build and develop effective relationships with stakeholders and the public, based on trust (a) To capture and evaluate stakeholder opinion (b) To increase the public awareness of the HTA (c) To manage the reputation of the HTA effectively																		
KPI 2.1	a	Comms	To evaluate public and professional opinions about the HTA.	Milestone/ Measure	Complete an evaluation of public and professional opinions about the HTA (to inform strategy) by end of Q2. Maintain or increase the proportion of professional stakeholders with confidence in the HTA and the regulation of human tissue relative to the previous survey.	G	G	G	G	G	B	B	B	B	B	B	B	(Jul) Findings will be presented at the September Authority meeting. (Aug) Paper to be presented at the September Authority meeting. (Sep) Activity complete
3. Be informed, influential and active in the environment in which we operate (a) To develop more effective horizon-scanning and knowledge management arrangements (b) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with the five licensable sectors (c) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with consent and organ donation (d) To contribute to the development and review of relevant legislation.																		
KPI 3.1	b	Res	To develop the licence fees structure for 2011/12.	Milestones	Consult licence fee payers and other interested parties about proposals by end of Q1. Communicate licence fees structure by end of Q2.	G	G	G	G	G	B	B	B	B	B	B	B	(Jul) Authority agreed fee structure at July meeting and further work required on fee level and on target for completion. (Aug) Communication of new fees to be distributed to establishments by the end of September. Policy and procedures currently being written. (Sep) Activity complete
4. Have motivated and dedicated staff with the right skills in the right jobs (a) To recruit, lead and motivate staff to deliver high quality work (b) To deliver a high quality learning and development programme (c) To develop an environment and culture which encourages continuous improvement and upholds the organisation's values																		
KPI 4.1	a	CEO	To implement targeted retention initiatives to maintain the annual attrition rate at 18%.	Measure	Attrition rate (measured monthly on rolling annual basis). Target rate 18%.	23%	27%	25%	27%	24%	30%	30%	35%	35%	37%	33%	(Oct) 1 Nov 2009 to 31 Oct 2010 start headcount 54, end headcount 45 and 15 leavers. (Nov) 1 Dec 2009 to 30 November 2010 start headcount 54, end headcount 44 and 17 leavers. (Dec) 1 Jan 2010 to 31 December 2010 start headcount 54, end headcount 43 and 17 leavers.	
5. Continuously improve the way the HTA is governed and managed (a) To further develop governance arrangements (b) To continuously review systems, processes and procedures to find ways of working more economically, efficiently and effectively (c) To ensure the continued financial viability of the HTA																		
KPI 5.1	a/b	Regs Pol	To extend the HTA's publication scheme under the Freedom of Information Act to improve organisational transparency and accountability.	Milestone	Project plan for publication of significant regulatory action, licensing status and inspection reports developed by end of Q1. Publication of inspection reports to begin in November 2010.	G	G	G	G	G	G	G	G	G	B	B	B	(Oct) Paper was presented on progress at the September Authority meeting and new arrangements are on track. (Jan) Publication of inspection report went live at the end of January 2011.
KPI 5.2	c	Res	To manage the HTA's finances to ensure: sufficient funds in place to meet payments required; appropriate spending; and appropriate levels of reserves.	Measure	Reserves held are within 5% of planned level (Measured monthly).	NA	G	G	G	G	G	X	X	X	X	X	X	(Aug) The KPI needs revising as the definition of Reserves needs to be agreed. Due by end of October. (Sep) The KPI needs revising as the definition of reserves needs to be agreed. Due by end of October. (Oct) This KPI is discussed in the covering Authority paper.

Authority paper

Date	22 March 2011	Paper reference	HTA (18/11)
Agenda item	12	Author	Sue Martin

Financial report at end February 2011

Introduction

1. This paper provides a report of the HTA's financial position as at 28 February 2011, after eleven months of the financial year has elapsed.
2. The report provides commentary on the following areas:
 - budget constraints
 - overview of financial position to 28 February 2011
 - income and expenditure variances
 - forecast outturn
 - other key performance indicators
 - financial risks

Budget constraints

3. The Department of Health (DH) has confirmed that the 33% reduction over three years will be applied to arm's length bodies (ALBs). DH has issued the indicative 2011/12 Grant-in-aid (GIA) budget - a reduction of 10% as expected. We expect to receive additional GIA (of around £100k) for 2011/12, for the implementation of the Organ Donation Directive.

Overview of financial position at 28 February 2011

4. **Annex A** shows the summarised financial position for the year to 28 February 2011. At that date, there was an under-spend on revenue expenditure of **£932k** and also **£15k** more income in total than anticipated. Together these resulted in a gross surplus on the profiled budget of **£947k** before any exceptional items.

The main reason for the under-spend is that several posts have been left vacant this year, leading to reduced salary and other staff costs.

5. Exceptional items include adjustments to accruals made in 2009/10 for expenditure that did not happen and rebates of licence fee relating to financial years 2006/07 to 2009/10 of **£1,143k**. At the end of February, **£924k** had been paid over to establishments. Every effort is being made to pay the balance over before 31 March 2011.
6. The effect of the exceptional items leads to a surplus over budget within the year of **£122k** as at 28 February.
7. A review of expenditure has been undertaken this month, with emphasis on ensuring all costs are provided for and that there are no surprises at year-end. As we are a month away from year end more detailed reviews are not necessary.

Income – variances to 28 February 2011

8. **Annex B** provides a more detailed breakdown of income generated to 28 February 2011. In the eleven months, compared to budget, there is more income than expected in total. This is largely due to the revenue GIA being received earlier than profiled.
9. The final tranche of revenue GIA was received at the end of February 2011, slightly earlier than expected.
10. Capital GIA of **£103k** was also requested and received in February, for works on the new office, CRM and finance system development.
11. Licence fee income from all sectors has been less than expected, due to changes in the numbers of establishments since the budget was drawn up.

Expenditure – variances to 28 February 2011

12. **Annex C** shows expenditure as at 28 February 2011 for staff and non-staff costs. There is an overall under-spend of **£932k** before exceptional adjustments.

13. The main variances are summarised below:

Expenditure Variances		
	£	Notes
Staff costs	596,253¹	Posts have been kept vacant for efficiency and pending review.
Non staff costs	336,294	This variance is analysed in greater detail in the lines below.
Travel & subsistence	86,686	Cost per inspection less than budgeted.
Training & Recruitment	144,434	Primarily due to the lack of external recruitment.
Conference & Project costs	96,035	Reduced project activity due to constraints on spend and resource available.
Post, Stationery & Printing	35,523	Printing of inspection and other reports budgeted for are no longer being carried out. Efficiencies made in stationery by careful ordering.
Legal	(35,274)	Additional costs because of advice required.
Consultancy	52,129	Less activity than planned to date, partially due to financial controls and resources available.
Accommodation	(114,933)	Relocation costs not budgeted for.
Non Cash Costs	(47,365)	Write off of Finlaison House improvements not budgeted for.
Capital charges	92,490	Change in accounting treatment of depreciation resulted in charges being different to profile.
Other variances	26,568	

1 () denotes an over-spend

14. **Annex D** provides an analysis of expenditure by Directorate. Directorates are under-spending because of staff vacancies and the reasons above.

Forecast outturn

15. As summarised in Annex A, year-end income is expected to be £250k (3.9%) less than budgeted over the year as a whole, due to changes in the numbers of establishments paying licence fee.

16. Expenditure is expected to be less than budgeted due to financial constraints, efficiencies and adjustments from 2009/10. The forecast surplus before exceptional items is now **£816k** (12.8%). The forecast surplus has increased since last month due to the accounting treatment of cost of capital.

Other key performance indicators

Reserves

17. Total reserves at the end of February are £4.0m and our cash balance is £3.5m. We intend to credit establishments with surplus licence fee income, in proportion to the fees they have paid in 2010/11. We will provide details of the individual amounts to establishments early in April. This credit will be offset against 2011/12 fees and we will arrange refunds for establishments who no longer have a licence.

Debtors

18. As at 28 February our licence fee gross debtor balance was **£125k**. Fees were outstanding from 19 establishments, including those recently granted licences. **52.8%** is due from public sector bodies and **47.2%** from private sector bodies (£66k public sector and £59k private sector).

19. As at 28 February four debtors are with our Head of Legal for further action, to recover £29k. One establishment has since paid £9.8k in settlement of their debt. The remaining three establishments come under one NHS Trust and it is expected that these debts will be settled very soon.

Prompt payment

20. For the eleven months ended 28 February, 99.2% of invoices were paid within 30 days of receipt of a valid invoice, 82% within 10 days and 62% within 5 days. Average payment time was 8.44 days. For the month of February 85.1% of invoices have been paid within the 5 day target.

Financial risks

21. Financial risks continue to be considered on an ongoing basis. 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 the Senior Management Team (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

22. The Authority is asked to note the financial position as at 28 February 2011.

Human Tissue Authority

Summary - Income & Expenditure

Annex A

For the Eleven Months Ending 28 February 2011

	Year to Date			FULL YEAR			
	Actuals £	Budget £	Variance £	Forecast £	Budget £	Variance £	%
INCOME & EXPENDITURE SUMMARY							
Income	(6,143,120)	(6,128,020)	(15,100)	(6,143,120)	(6,392,770)	249,650	-3.91%
Less:							
Expenditure	4,858,342	5,790,302	(931,960)	5,327,265	6,392,770	(1,065,506)	-16.67%
Gross (surplus)/deficit of income over expenditure	(1,284,778)	(337,718)	(947,060)	(815,856)	0	(815,856)	
Exceptional items							
Internal adjustments	(98,965)	0	(98,965)	(98,965)	0	(98,965)	
2006-2010 Rebate	924,242	0	924,242	1,143,000	0	1,143,000	
Total Exceptional Items	825,277	0	825,277	1,044,035	0	1,044,035	
Net (surplus)/deficit of income over expenditure	(459,501)	(337,718)	(121,783)	228,179	0	228,179	

Human Tissue Authority

Member Income Summary

ANNEX B

For the Eleven Months Ending 28 February 2011

	Year to Date			FULL YEAR			
	Actuals £	Budget £	Variance £	Forecast £	Budget £	Variance £	%
Grant In Aid							
GIA	1,059,000	794,250	264,750	1,059,000	1,059,000	0	0.00%
Sub-Total	1,059,000	794,250	264,750	1,059,000	1,059,000	0	0.00%
Licence Fees							
Anatomy	233,675	247,650	(13,975)	233,675	247,650	(13,975)	-5.64%
Post Mortem	1,800,000	1,896,000	(96,000)	1,800,000	1,896,000	(96,000)	-5.06%
Public Display	26,870	42,930	(16,060)	26,870	42,930	(16,060)	-37.41%
Research	901,800	947,100	(45,300)	901,800	947,100	(45,300)	-4.78%
Human application	2,021,000	2,100,800	(79,800)	2,021,000	2,100,800	(79,800)	-3.80%
Sub-Total (surplus)	4,983,345	5,234,480	(251,135)	4,983,345	5,234,480	(251,135)	-4.80%
Other							
Other income	554	0	554	554	0	554	
Scottish & N. Ireland Execs. & Welsh Assembly	100,221	99,290	931	100,221	99,290	931	0.94%
Sub-Total	100,775	99,290	1,485	100,775	99,290	1,485	1.50%
Total Income	6,143,120	6,128,020	15,100	6,143,120	6,392,770	(249,650)	-3.91%

Human Tissue Authority

Summary - Expenditure

Annex C

For the Eleven Months Ending 28 February 2011

	Year to Date			FULL YEAR			
	Actuals £	Budget £	Variance £	Forecast £	Budget £	Variance £	%
EXPENDITURE SUMMARY							
Staff Costs	2,870,869	3,467,121	(596,253)	3,111,936	3,777,066	(665,130)	-17.61%
Non Staff Costs	1,987,474	2,323,181	(335,707)	2,215,329	2,615,704	(400,376)	-15.31%
Gross (surplus) Costs before Exceptional Items	4,858,342	5,790,302	(931,960)	5,327,265	6,392,770	(1,065,506)	-16.67%
Exceptional items							
Internal adjustments	(98,965)	0	(98,965)	(98,965)	0	(98,965)	
2006-2010 Rebate	924,242	0	924,242	1,143,000	0	1,143,000	
Total Exceptional Items	825,277	0	825,277	1,044,035	0	1,044,035	
Total Expenditure	5,683,619	5,790,302	(106,683)	6,371,299	6,392,770	(21,471)	-0.34%

Human Tissue Authority

Directorate Summary

Annex D

For the Eleven Months Ending 28 February 2011

	Year to Date				FULL YEAR			
	Actuals £	Budget £	Variance £	%	Forecast £	Budget £	Variance £	%
Communications	349,909	428,473	(78,564)	-18.34%	371,219	470,089	(98,870)	-21.03%
Regulation	935,306	1,165,980	(230,675)	-19.78%	1,005,746	1,274,756	(269,010)	-21.10%
Policy	882,675	1,228,894	(346,219)	-28.17%	954,032	1,338,868	(384,836)	-28.74%
HTA Board	151,844	231,371	(79,527)	-34.37%	166,139	277,859	(111,720)	-40.21%
Resources	2,098,755	2,147,195	(48,440)	-2.26%	2,352,489	2,395,359	(42,870)	-1.79%
Chief Executive's Office	439,854	588,389	(148,535)	-25.24%	477,639	635,840	(158,201)	-24.88%
Subtotal (surplus)	4,858,342	5,790,302	(931,960)	-16.10%	5,327,265	6,392,770	(1,065,506)	-16.67%
Exceptional adjustments	(98,965)	0	(98,965)		(98,965)	0	(98,965)	
2006-2010 Rebate	924,242	0	924,242		1,143,000	0	1,143,000	
	825,277	0	825,277		1,044,035	0	1,044,035	
Total Directorate(s) Expenditure	5,683,619	5,790,302	(106,683)	-1.84%	6,371,299	6,392,770	(21,471)	-0.34%

Authority paper

Date	22 March 2011	Paper reference	HTA (19/11)
Agenda item	13	Author	Sue Martin

Report from the Audit Committee February 2011

Purpose of paper

1. This paper highlights the key points discussed at the Audit Committee on 11 February. The minutes of the meeting are at Annex A.

Recommendations

2. That Authority Members note these issues and raise any queries.

Key Points

3. **Debtors** – There has been significant progress in speeding up payments of licence fee. The Head of Legal explained to the Committee the action she takes and the position with debtors referred to her. She has instigated court action on one case, resulting in the debtor paying before the hearing.
4. **Risk Management** – The Committee reviewed the updated strategic risk register and discussed risks with Alan Clamp, in particular the impact of staff leaving and new staff on delivering the HTA's statutory remit. Alan confirmed that action is in hand to ensure this is not compromised.
5. **Internal audit** – Three audit reports had been finalised and were reviewed by the Committee. Good progress had been made on previous risk management recommendations. Internal audit had made further recommendations and the Committee were concerned that these should be implemented in a proportionate way that is suitable for the HTA.
6. **External audit** – The National Audit Office outlined their strategy for the audit of the 2010/11 accounts. The interim audit took place from 28 February to 11 March.

7. **Internal auditors** – The Committee is exploring sharing the Department of Health's (DH) internal auditors, Grant Thornton. Members will meet the audit team to discuss their approach

8. **Shared services** – The Committee discussed the DH led work towards shared business services and asked to be kept informed of developments.

Minutes of Audit Committee

AUD 01-11

Date 11 February 2011
Venue Human Tissue Authority
 151 Buckingham Palace Road
 Victoria, London, SW1W 9SZ

Present

Members

Professor Michael Banner (Chair)
 Ms Pamela Goldberg
 Mr Brian Coulter
 Ms Suzanne McCarthy

In attendance

Mrs Sue Martin (Director of Resources)
 Mr Craig Muir (Chief Executive)
 Ms Morounke Akingbola (Head of Finance)
 Miss Nicola Harlow (Finance Manager)
 Alan Clamp (Director of Regulation)
 Helen Holmes (Head of Legal)
 Mr Patrick Irwin (Department of Health)

National Audit Office

Paul Holland

RSM Tenon

Stuart Hopkinson

Item 1 – Welcome and Apologies

1. Professor Susan Dilly was absent from the meeting.

Item 2 – Declarations of Interest

2. None declared.

Item 3 – Minutes from 12 November 2010 (AUD 25-10)

3. Minutes were agreed.

Item 4 – Matters arising

4. Sue Martin provided progress on actions from the November Meeting:

- Page 3
 - The Risk Management policy wording has been amended.
- Page 4
 - Suspension of licences will be raised in April as a potential area for internal audit in 2011/12.
- Page 5
 - The status of audit tracker recommendations is now consistent throughout the annexes.
- Page 5
 - The NAO audit strategy was distributed at the meeting.

Item 5 – Updated Policies

Financial Procedures Manual (AUD 26-10)

5. Morounke presented the Financial Procedures Manual (FPM) to the Committee, highlighting the changes because of the move from Sage to Great Plains accounting systems. The Updated FPM also includes hyperlinks to make the contents more accessible to staff.
6. The Committee requested minor clarifications and these will be incorporated into the FPM.
7. The rationale behind the credit card limit of £15,000 was questioned and Morounke explained that it represented £5,000, a standard amount, per Director for whom cards have been agreed. Credit card use does not exceed these levels.

Procurement Policy (AUD 27-10)

8. Morounke Akingbola presented the updated Procurement policy for the Committee to note. A minor wording change is to be made (in paragraph 3, from 'asked' to 'required').

Tender Policy (AUD 28-10)

9. Morounke Akingbola presented the updated Tender policy for the Committee to note.

10. The arrangements for opening tenders were discussed and it was agreed that they are adequately reflected in the policy. More robust procedures may be necessary if a major exercise ever took place.

Action 1

Morounke Akingbola to amend the wording of the Financial Procedures Manual and Procurement Policy.

Item 6 – Debtors Update (AUD 29-10)

11. Morounke presented the Debtors paper, drawing the Committees attention to the table on page 3, showing the improvement in the debt collection process throughout the year.
12. Helen Holmes, Head of Legal, presented to the Committee the process of debt collection and legal action, highlighting the change in the SOP from referral to Regulation to referral to Legal.
13. Helen explained that the HTA has sued one establishment, with a successful recovery of annual fees for two years plus court costs and interest. Helen also explained that she can take legal action on-line, minimising both the cost to the HTA (which is fully recovered if the claim is successful) and time taken by the Head of Legal.
14. The Committee noted the good progress in recovery of debts and raised a question regarding the ~~de~~ minimum level of debt properly pursued by legal means. Helen explained that fortnightly debtor meetings, between Legal, Finance and the Licensing team, ensure that appropriate decisions are made.

Item 7 – Risk Update (AUD 30-10)

15. Sue Martin presented the Strategic Risk Register which is reviewed monthly by the Senior Management Team. It was agreed that the explanation in the narrative provides the Committee with information they need about changes in risk status.
16. The risk of ‘failure to manage change’ was discussed, and in particular the impact of staff attrition on the HTA’s ability to continue its statutory functions. The Committee was informed that most attrition is routine rather than a reaction to the ALB review and the Director of Regulation confirmed that the HTA’s ability to fulfil its statutory duty has not been compromised.

17. Alan Clamp (Director of Regulation) reported to the Committee the areas that concern him and outlined several steps he plans to take forward to mitigate risks.
18. The Committee discussed the risk of HTA standards dropping as staff levels fall and Alan explained that new members of staff would be adequately trained and would undertake inspections with another experienced lead inspector until enough experience had been gained to work in a lead role.
19. Alan also informed the Committee that a new reporting method of 'exception based reporting' is being used which will reduce time spent on composing reports without compromising the quality of the HTA's work or standards.

Item 8 – Internal Audit

Progress Report (AUD 31-10)

20. Stewart Hopkinson presented the Progress Report highlighting the Data Protection, Risk Management and Core Financial Controls reports that have been completed. He explained that the Head of Internal Audit will provide the overall audit opinion at the next meeting.
21. The Committee noted the positive Risk Management report and the progress that has been made. It was agreed that the implementation of the recommendations from the report should take account of the nature and size of the HTA and hence be proportionate.

Item 9 – Audit Tracker (AUD32-10)

22. Nicola Harlow took the Committee through the audit tracker, highlighting the inclusion of the recommendations from the most recent audit reports.
23. The Committee noted the progress made.

Item 10 – External Audit Update

24. Paul Holland briefed the Committee about the strategy for the 2010/11 audit that was circulated at the meeting.
25. The NAO audit fee will be at the same level as last year and any cost savings that the NAO make will be passed on.

Item 11 – Efficiencies (AUD 33-10)

26. Sue Martin presented to the Committee the HTA's draft efficiency plan for 2012/13 that has been submitted to the Department of Health with the business plan. The Committee were content.
27. The Committee discussed shared business service proposals being made by the Department of Health.

Action 2

Sue Martin to update the Audit Committee at the June meeting on the position with shared business services.

Item 12 – Review of Audit Committee Terms of Reference (AUD 34/10)

28. The Committee agreed that no amendments were necessary.

Item 13 – A.O.B

29. Sue Martin reported that there were no identified cases of fraud or suspected fraud.

Item 14 – Update for Members

30. Sue Martin updated the Committee regarding plans for internal audit after the current contract with RSM Tenon ends. Sue had met Grant Thornton, a firm of internal auditors already used within the Department of Health and available to the HTA as a shared service.
31. Sue proposed that a member of the Audit Committee alongside the Chair, Michael Banner, should meet with the audit team of Grant Thornton to decide on the appointment of the auditors. It was agreed that Pamela Goldberg will attend.
32. It was suggested that Grant Thornton should be invited to present their approach, and be provided with the HTA risk register to inform their proposals. Sue will make the arrangements.

The meeting closed at 11.55am

Authority paper

Date	22 March 2011	Paper reference	HTA (20/11)
Agenda item	14	Author	Fiona McKinson

Enquiries report

Purpose of paper

1. This paper accompanies the quarterly enquiries report for the period 1 December 2010 – 28 February 2011 (Annex A).

Action

2. Authority Members should note the content of the report and provide any comments.

Key findings

3. Some key observations from this quarter follow:
 - i. We received fewer enquiries than in the previous quarter – 750 compared with 907 between 1 September 2010 and 30 November 2010. We also received 26 % fewer enquiries compared with equivalent quarter in 2009/10; 750 compared with 945.
 - ii. 98% of enquiries were responded to within the 20 working day deadline. The average response time was five days. In February we responded to 100% of enquiries within the deadline.
 - iii. As in previous reports, we received more enquiries by phone than any other channel and more enquiries on body donation than on any other subject area.
 - iv. The number of body donation enquiries in the last quarter is relatively consistent with that in previous quarters despite the implementation of the new body donation webpage which makes it easier for the public to find their local medical school. This service has been publicised in the e-newsletter

and via medical schools, although there is still more to do to promote the service.

- v. The complaint received in January was from a licensed establishment regarding publication of inspection reports and it has been addressed directly by Alan Clamp, Director of Compliance and Enforcement.
- vi. The three Parliamentary Questions this quarter related to the size of our communications team (four people), whether or not we have had any contracts with Addison Lee (no) and what steps we have taken to comply with the Guidance of the Office of Government Commerce on promoting skills through public procurement issued in 2009 (a nil response).
- vii. Over the year we have seen the number of enquiries fall. This may be related to our Customer Relationship Management (CRM) system which was launched in March 2010. We are aware that some staff still have training needs in relation to the new system and refresher sessions have been set up accordingly.
- viii. A project in the 2011 business plan will review the enquiries system. New targets for responding to enquiries have been set in the new corporate business plan.
- ix. Over the year the number of professional enquiries has fallen as the number of public enquiries has risen.

Using the enquiries data

- 4. The enquiries data are used to inform the development of new advice and guidance. Our website guidance on consent for DNA analysis arose out of enquiries on the subject. We are also considering producing additional guidance on DNA due to a further increase in enquiries. Other guidance, on recipients who lack capacity to consent to organ donation, will be produced by summer 2011.
- 5. We have also used the enquiries data to inform a cross-organisational project, in which we reviewed all website pages and developed new content. This project is formally completed but the website is ever-evolving.

Annex

HTA quarterly enquiries report December 2010 – February 2011

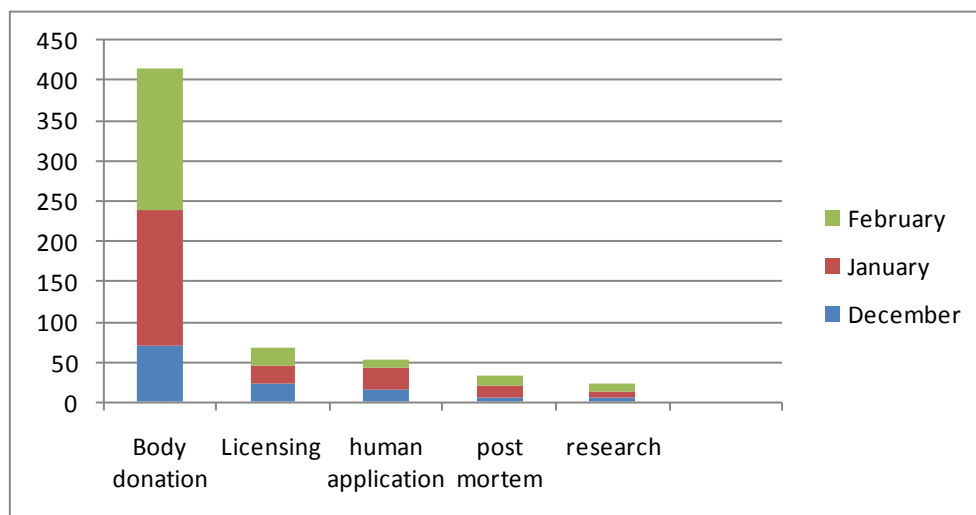
Response times

98% of enquiries were responded to within the 20 working day deadline. Over the three month period the average response time was five days.

Subject of enquiries by month

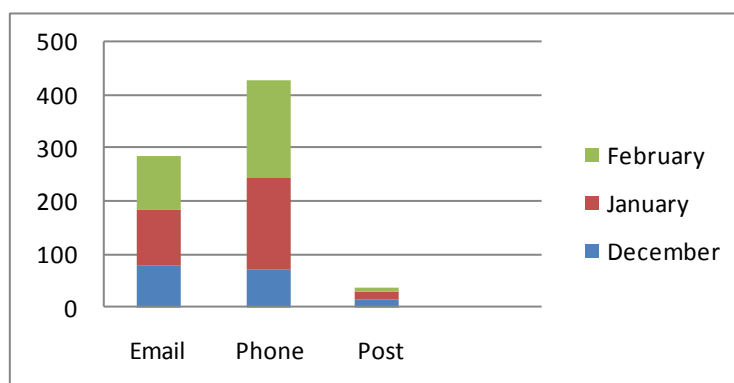
The top five subjects for enquiries over the quarter were:

- 415 body donation
- 67 licensing
- 54 human application
- 34 post mortem
- 23 research



Type of enquiry by month

751 enquiries were recorded in the enquiries log between 1 December 2010 and 28 February 2011; 427 of these were received by phone, 286 by email, 37 by post and one face-to-face.



Overview of enquiries by month

	Quarter	Month		
	Total Dec 2010 – Feb 2011	December 2010	January 2011	February 2011
Total	750	160	296	295
Professional	286	77	109	101
Public	183	29	65	89
Media	18	4	8	6
Not-specified	264	50	115	99
Channel				
Email	286	76	109	101
Phone	427	69	173	185
Face-to-face	1	1	0	0
Post	37	14	14	9
Fax	0	0	0	0
Website	N/A	N/A	N/A	N/A
Response times				
Deadline met	98%	97%	98%	100%
Average (days)	5	5	6	3
Subject				
Accommodation	0	0	0	0
Anatomy	5	2	2	1
Body donation	415	70	170	175
Bone marrow donation	1	1	0	0
Business and strategy	1	0	1	0
Communications	4	3	0	1
Complaints	1	0	1	0
Consent	15	5	5	5
Contracts	0	0	0	0
Data protection	0	0	0	0
Directions	0	0	0	0
Disposal	3	0	3	0
DNA	12	2	3	7
Enquiries	1	1	0	0
Ethics	1	1	0	0
Fees	3	1	1	1
Finance	5	1	4	0
Freedom of Information	10	0	3	7

Governance	0	0	0	0
Human Resources	1	0	1	0
Human application	54	17	26	11
Import and export	15	2	5	8
Inspections	2	0	1	1
Information Technology	9	1	4	4
Knowledge and quality management	3	0	2	1
Legal advice	1	0	1	0
Legislation	5	0	2	3
Licensing	67	24	21	22
Organ transplants	21	5	6	10
Parliamentary Questions	3	2	0	1
Post mortem	34	6	14	14
Purchasing	0	0	0	0
Public display	7	1	2	4
Reporting	3	1	2	0
Research	23	6	8	9
Service Level Agreements / Third Party Agreements	6	3	1	2
Storage	16	3	5	8
Testing	3	1	2	0

Overview of enquiries by quarter

	Quarter				
	Total Dec 2009 – Feb 2010	Total March – May 2010	Total June– Aug 2010	Total Sept– Nov 2010	Total Dec 20– Feb 2011
Total	945	1017	1330	907	751
Professional	*	424	357	340	286
Public	*	171	170	131	183
Media	61	35	23	26	18
Not-specified	*	387	780	410	264
Channel					

Email	246	328	369	267	286
Phone	267	528	881	588	427
Face-to-face	2	0	2	-	1
Post	4	67	76	52	37
Fax	0	0	0	-	0
Not-specified		94	2	-	N/A
Response times					
Deadline met	99%	76%	97%	96%	98%
Average (days)		5	5	6	5
Subject					
Accommodation	0	0	0	0	0
Anatomy	12	13	17	11	5
Body donation	426	595	865	513	415
Bone marrow transplants	4	0	2	2	1
Business and strategy	1	0	0	0	1
Communications	0	3	2	10	4
Complaints	0	0	1	0	1
Consent	33	17	9	21	15
Contracts	0	0	0	0	0
Data protection	4	0	0	0	0
Directions	0	2	0	0	0
Disposal	9	13	20	12	3
DNA	5	8	16	13	12
Enquiries	0	0	0	1	1
Ethics	1	9	5	1	1
Fees	4	1	2	2	3
Finance	0	2	2	4	5
Freedom of Information	2	1	11	3	10
Governance	0	1	0	1	0
Human Resources	0	2	0	0	1
Human application	55	58	45	49	54
Import and export	12	12	9	15	15
Inspections	7	1	2	6	2
Information Technology	7	6	0	3	9
Knowledge and quality management	9	4	3	3	3
Legal advice	0	1	2	0	1

Legislation	16	9	10	8	5
Licensing	99	93	89	94	67
Organ transplants	36	24	27	9	21
Parliamentary Questions	1	0	5	2	3
Post mortem	53	42	101	59	34
Purchasing	1	0	0	0	0
Public display	13	11	1	8	7
Reporting	2	1	1	3	3
Research	50	50	61	43	23
Service Level Agreements / Third Party Agreements	6	6	7	4	6
Storage	11	10	10	4	16
Testing	N/A	4	2	1	3

**Please note that as the CRM system was not launched until March 2010, there are no data available between December 2009 and February 2010 providing the number of professional, public or unspecified enquiries.*