

Forty-seventh Meeting of the Human Tissue Authority

Date 25 January 2011

Time 10.30am – 1.00 pm

Venue HTA Boardroom
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 23 November 2010 HTA (01/11)
4. Matters arising
5. Chair's report Oral
6. Strategic performance review December 2010 HTA (02/11) AMS
(I)
7. Financial report December 2010 (I) HTA (03/11) SM
8. Criteria for judging ALB review options (D) HTA (04/11) CM
9. Post mortem sector audit of retained material (I) HTA (05/11) AC
10. Significant regulatory activity report – 1 October HTA (06/11) AC
to 31 December 2010 (I)
11. Summary of post-inspection feedback for 2010 HTA (07/11) AC
(I)
12. Domino paired living organ donation (D) HTA (08/11) SG
13. HTA Policy on composite tissue (I) HTA (09/11) SG
14. Operation of the living organ donation system (I) HTA (10/11) SG
15. Update on non-genetically or emotionally related Oral SG
directed donation (I)
16. Any other business



Minutes of the forty sixth meeting of the Human Tissue Authority

Date 23 November 2010
Venue HTA Boardroom
 15-17 Furnival Street
 London
 EC4A 1AB

Present	
<p>Members Baroness Diana Warwick (Chair) Professor Michael Banner Mrs Jodi Berg Mr Brian Coulter Professor Susan Dilly Mrs Rosie Glazebrook Mrs Pamela Goldberg Mrs Suzanne McCarthy Professor Gurch Randhawa Mr Keith Rigg Ms Catharine Seddon</p>	<p>In attendance Dr Shaun Griffin (Director of Communications and Public Affairs) Ms Liz McAnulty (Interim Director of Compliance and Enforcement) Mrs Sue Martin (Director of Resources) Mr Allan Marriott-Smith (Authority Secretary)</p> <p>Ms Sara Coakley (Senior Media and Public Affairs Manager) Ms Imogen Swann (Head of Regulation)</p> <p>Observers Mr Peter Jones (Department of Health)</p>

Item	Title	Action
Item 1	Welcome and apologies	
	1. Baroness Warwick welcomed Members and observers to the forty-sixth meeting of the Human Tissue Authority. 2. Apologies had been received from Mr Craig Muir and Dr Andrew Reid.	
Item 2	Declarations of interest	
	3. There were no declarations of interest.	
Item 3	Minutes of 28 September [paper: HTA (43/10)]	
	4. The minutes of 28 September were adopted.	
Item 4	Matters arising	
	5. Members were informed that the Minister is due to make a decision on which organisation will become the Competent Authority for the EU Organ Donation Directive in January 2011.	
Item 5	Chair's report	
	6. The Chair provided the Authority with an oral report on the Parliamentary Brief issued by the British Medical Association (BMA) on 19 November to coincide with the House of Lord Committee Stage of the Public Bodies Bill. The position described in the Brief ran contrary to that previously expressed to the Chair and the Executive. In discussion, Authority Members expressed concern about this change in stance and identified an urgent need to establish the reasons for this. Action: The Chair to write to Dr Hamish Meldrum (Chair of the BMA) seeking clarification on the reasons for the change in position. Action: The Executive to work with BMA operational contacts to identify the stakeholder concerns which resulted in the position described in the Parliamentary Brief.	DW SG
	7. The HTA ran a conference for the Human Application sector in Nottingham on 21 October. This was attended by a number of influential organisations in the sector and a range of both national and international speakers. The event had been extremely well received by attendees.	
	8. The Chair met the Parliamentary Under Secretary of State	

	<p>for Public Health on 26 October to discuss issues stemming from the arm's-length body (ALB) review.</p> <p>9. The Chair met with Professor Lisa Jardine, Chair of the Human Fertilisation and Embryology Authority, on 8 November to discuss issues of common interest in relation to the ALB review.</p> <p>10. The Chair attended the annual dinner hosted by the Royal College of Pathologists on 10 November.</p> <p>11. The HTA held a team awayday on 11 November. The Chair attended a session on the implications of the ALB review and spoke about the importance of people in the delivery of HTA business over the coming months and years.</p> <p>12. Lord Howe hosted an ALB Transition Programme event for the Chairs of arm's-length bodies on 22 November.</p> <p>13. The Chair asked Members to note that a case which is currently subject to regulatory activity by the HTA has the potential to generate media interest. The Chair will provide the Authority with more detail should this look likely to occur.</p>	
Item 6	ALB review options appraisal [paper: HTA (44/10)]	
	<p>14. Shaun Griffin introduced the paper which had been produced to assist the Authority in identifying the governance and management issues which are likely to arise from the transfer of HTA functions following the ALB review. The paper had been produced with input from a number of stakeholders from our regulated sectors and from HTA staff.</p> <p>15. In discussion, a number of issues were raised and clarifications made:</p> <ul style="list-style-type: none"> i. At the end of paragraph 4 “protect the interests of the HTA team” refers to the protection of staff interests as part of any TUPE transfer to other organisations. ii. All of the options are likely to result in a dilution of the current non-executive board and the skills and experience that Members bring to bear in the governance of the HTA. Any new structure will need to ensure that robust governance arrangements are in place. iii. While input from patient groups had been sought, little had been received. The Authority was keen to know more about their views and the likely views of members of the general public. iv. The paper in its current form is helpful to aid Authority understanding and discussion, but should be adapted if it is to be used more widely to inform the debate around the best option for the future location of HTA functions. 	

	<p>v. Developing on this Authority paper, a new document should be produced which outlines the criteria against which the choices of future structure should be judged. This should include the need to protect the public interest as part of any transfer.</p> <p>Action: A paper should be produced for the January Authority meeting describing the criteria against which the choices of future structure should be judged.</p>	SG
Item 7	Update on plans following HTA action at Cardiff & Vale University Health Board [paper: HTA (45/10)]	
	<p>16. Shaun Griffin introduced the paper, which described the progress made with the actions resulting from the lessons learnt following the HTA action at Cardiff and Vale University Health Board.</p> <p>17. The Authority welcomed the paper, the proactive action being taken and the attempt being made to address the residual concerns of a number of HTA stakeholders.</p> <p>18. On a point related to action 4 in the paper, Liz McAnulty reported that she had undertaken a discussion with Dr Andrew Reid regarding his concerns in relation to evidence collected under the Police and Criminal Evidence (PACE) Act and the Coroners Rules. A paper will be produced for the January meeting describing the issues which give rise to Dr Reid's concerns, the HTA remit in this area and the steps which the HTA has taken to try to improve the situation.</p> <p>Action: A paper on the issues stemming from PACE and the Coroners Rules to be produced for the January Authority meeting.</p> <p>19. Communication of these outcomes with stakeholders in the post mortem sector will take place in the first half of December. This communication will be informed by comments made by the Authority during this discussion.</p> <p>20. The HTA Histopathology Working Group will meet for the first time in January. At the HTA's invitation, the Royal College of Pathologists has nominated members to join this group.</p> <p>Action: The Executive to provide the Authority with a list of members of the HTA Histopathology Working Group</p>	LM SG
Item 8	Draft Strategic Plan 2011/12 to 2013/14 [paper: HTA (46/10)]	
	<p>21. Allan Marriott Smith introduced the paper which presented the most recent draft of the HTA's strategic aims and high level business objectives for 2011/12 to 2013/14. This draft had been developed based on the Authority's strategic review which was undertaken at its awayday in September.</p>	

	<p>22. Members agreed the aims and objectives subject to a number of small drafting changes. These will be used as the basis for detailed planning for the business year 2011/12.</p> <p>Action: Drafting changes to be made to the strategic aims and high level objectives in line with Authority Member comments. The final version of the Strategic Plan will be brought to the March Authority meeting.</p>	AMS
Item 9	Strategic Risk Register [paper: HTA (47/10)]	
	<p>23. Sue Martin introduced the paper which presented an update of the strategic risk register following a review undertaken by the Authority at its awayday in September. Comments had been received at the Audit Committee in November and these will be incorporated by the end of December.</p> <p>24. Members noted the changes and asked that a further assessment be made of the impact scoring for the risk 'failure to manage change' to ensure that the residual risk score is appropriate in light of the actions being taken to manage the risk.</p> <p>Action: Further assessment to be made of the strategic risk failure to manage change.</p>	SM
Item 10	Significant regulatory activity report – 1 July to 30 September 2010 [paper: HTA (48/10)]	
	<p>25. Liz McAnulty introduced the paper. This report has been greatly enhanced over recent months, to provide the Authority with greater insight into the HTA's regulatory activity. This quarter's report also provided the Authority with details of the changes being made to the structure of HTA inspection reports, to coincide with their regular publication (beginning at the end of January 2011).</p> <p>26. The Authority considered the content of the report and made a number of comments:</p> <p>i. This report is too detailed for full consideration by the Authority. Members proposed that the report should come to the Authority for information following a more detailed consideration by the Regulation Members Group.</p> <p>Action: The Executive to consider the most appropriate timing for the next meeting of the Regulation Members Group.</p> <p>ii. Following the audit of holdings undertaken by establishments in the post-mortem sector, an analysis of the data is currently being undertaken by the Executive.</p> <p>Action: A paper describing the main findings for the audit undertaken by post-mortem establishments to be presented</p>	

	<p>at the January Authority meeting.</p> <p>iii. Members sought, and received assurances, that lessons learnt from regulatory activity, SAEARs and SUIs are communicated to licensed establishments to assist them in better meeting our standards.</p> <p>iv. The Executive should begin to monitor compliance with the requirement to report SAEARS within twenty four hours, and evaluate whether this is appropriate in all cases. These findings should be reflected in future reports.</p>	
Item 11	Financial report October 2010 [HTA (49/10)]	
	27. The paper was accepted for information. Members suggested that further assurance was required on the debtor position. The Authority agreed to delegate this discussion to the Audit Committee.	
Item 12	Strategic performance review October 2010 [HTA (50/10)]	
	28. The paper was accepted for information and there were no questions from Members.	
Item 13	Report from the Audit Committee November (51/10)]	
	29. The paper was accepted for information and there were no questions from Members.	
Item 14	Any other business	
	<p>30. Given the large number of issues facing the Authority requiring strong stakeholder management, Members requested that a Communication Members Group meeting be arranged.</p> <p>Action: The Executive to consider the most appropriate timing for the next meeting of the Communications Members Group.</p>	SG

The meeting closed at 1.00 pm



Authority paper

Date	25 January 2011	Paper reference	HTA (02/11)
Agenda item	6	Author	Allan Marriott-Smith

Strategic Performance Review – December 2010

Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during December. 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 the following approach in 2010/11:
 - i. 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.
 - ii. Improved narrative supporting KPIs will be enhanced to better explain the messages behind the indicators, in particular whether they raise issues of strategic concern.
 - iii. Improved ad hoc briefing throughout the year focussing in greater detail on performance issues in relation to each of the five strategic aims.

Strategic Performance Review of KPIs – Highlights December 2010

Compliance and Enforcement Policy and Compliance

4. KPI (1.2) for ***the proportion of additional licensing conditions in breach*** was red as 4 out of 12 (33%) of license conditions had not been compliance assessed within 28 days. This is a result of two establishments in the Human Application sector. In one establishment three conditions remain open. The DI has been contacted a number of times to provide us with this information but has not complied. The RM responsible for dealing with these conditions continues to pursue the DI. The other condition relates to an establishment which has provided compliance information. However, the RM responsible for assessing the condition is inspecting the establishment in February and will make an assessment at the site visit inspection. No further action is deemed necessary at this stage.
5. The Authority has previously noted that this KPI has not proved particularly successful as a measure of improvements in meeting HTA quality standards. This, coupled with the fact that the HTA has moved away from conditions as the main mechanism for raising standards, means that this KPI will not be continued in the next business year.
6. KPI (1.4) for ***95% of planned Human Application sector establishment inspections completed by Q4 is classified*** as amber as 57 out of 61 (93%) inspections had been undertaken by the end of December. This is because we expect one licence to be revoked and we have yet finalise plans for two joint MHRA inspections. The projection for the end of the year is 88 out of 91 (97%) inspections completed.

Communications and Public Affairs Transplants

7. All KPIs are on track.

Resources

8. All KPIs are on track.

CEO

9. 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 remains at 35%, which nearly twice the 18% target rate. The calculation is for 1 January 2010 to 31 December 2010 with a start headcount of 54, end headcount 43 with 17

leavers in this twelve month period. (Previous three figures were: year to end November - 35%, year to end October – 30%, year to end September – 30%). In addition the headcount over the month was down one from 44 to 43. Prior to the restrictions placed on recruitment, the HTA had been authorised to recruit to a full complement of 66 posts. SMT currently has approval from the DH's Recruitment Oversight Committee (ROC) to recruit to five posts, and have taken the active decision to leave a number of posts vacant.

10. The Authority will also wish to note that of the 43 staff employed at the end of December 2010, the **average time in post** was 27 months, a two month increase on the average reported last month.
11. The Authority has previously noted a range of measures which the HTA has in place to encourage staff retention (reference: paper HTA (29/10)).
12. The Authority will also wish to note that following the HTA staff survey undertaken in 2010, a working group comprising members of the team was formed to make proposals to address issues stemming from the survey. In particular, the group focussed on four interlinked issues: motivation; attrition; feedback and reward; and trust and confidence in SMT.
13. A number of actions were identified by the group and discussed and agreed with SMT. These actions will continue during this year, but some changes already made include:
 - The flexible working policy has been reviewed and will allow greater flexibility in working patterns;
 - The CEO and SMT now sit regularly with their teams in the open plan office to improve visibility and to promote a greater sense of one HTA;
 - A staff newsletter has been developed and sent from SMT fortnightly to give feedback from SMT meetings, showcase particular successes in individuals' work, and highlight any interesting stories about staff, new joiners and leavers.
 - Vacancies are now advertised internally first wherever this is practical.
 - The current social committee will recruit new voluntary members from all staff.

Strategic Performance Review December 2010																		
Strategic Aim																		
Unique ref	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																		
(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)			
						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)			(Oct) All 8 conditions relate to a single establishment. The explanation of this is provided in the covering Authority paper. (Dec) Four conditions relating to two establishments. The explanation of this is provided in the covering Authority paper.
						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)			
						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)			
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				
					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				
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			(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				
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%				
					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%				

Strategic Performance Review December 2010																	
Strategic Aim																	
Unique ref	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	(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	(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%			(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			(May) Draft project plan completed with a target date for publication of end September. (Oct) New style inspection reports went live from start of November 2010 and will be published in January. (Jun) Still on target for delivery by September. (Oct) Paper was presented on progress at the September Authority meeting and new arrangements are on track.
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	(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	25 January 2011	Paper reference	HTA (03/11)
Agenda item	7	Author	Sue Martin

Financial report at end December 2010

Introduction

1. This paper provides a report of the HTA's financial position as at 31 December 2010, after nine months of the financial year has elapsed.
2. The report provides commentary on the following areas:
 - budget constraints
 - overview of financial position to 31 December 2010
 - 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 (ALB). DH has now issued the indicative 2011/12 Grant-in-aid (GIA) budget - which includes a reduction of 10% as expected. GIA is the income the HTA receives from the Government.

Overview of financial position at 31 December 2010

4. **Annex A** shows the summarised financial position for the year to 31 December 2010. At that date, there was an under-spend of **£767k** on revenue expenditure and also **£332k** less income than anticipated. Together these resulted in a gross surplus of **£435k** on the profiled budget before any exceptional items.

5. Exceptional items include entries that adjust accruals made in 2009/10 for expenditure that will not happen.
6. Exceptional items also include the rebates of **£1,143k** relating to the financial years from 2006/07 to 2009/10. At the end of December, **£729k** had been paid over to establishments. The balance should be paid over before 31 March 2011, as we receive bank details from establishments.
7. The effect of the exceptional items leads to a surplus of **£195k** within the year as at 31 December.
8. This month a detailed review of spend and forecast outturn was conducted. This has resulted in agreement of likely spend, with under-spends in most categories increasing.
9. The recruitment freeze and other financial controls imposed by DH, and the HTA's efficiencies, continue to impact on spend, leading to under-spends. The impact on the delivery of business is reported separately.

Income – variances to 31 December 2010

10. **Annex B** provides a more detailed breakdown of income generated to 31 December 2010. Compared to budget, in the first nine months of the year, there is less income than expected in total.
11. The final tranche of revenue GIA will be requested in February 2011, as planned and before March year end.
12. Capital GIA will be drawn down in February for works on the new office and CRM and finance system development.
13. Income from the human application, post mortem and research sectors have been less than expected due to changes in the numbers of establishments since the budget was drawn up.

Expenditure – variances to 31 December 2010

14. **Annex C** shows expenditure as at 31 December 2010 for staff and non-staff costs. There is an overall under-spend of **£767k** before exceptional adjustments.

15. The main variances are summarised below:

Expenditure Variances		
	£	Notes
Staff costs	419,180¹	Posts have been kept vacant for efficiency and pending review.
Non staff costs	348,620	This variance is analysed in greater detail in the lines below.
Travel & Subsistence	65,958	Cost per inspection less than budgeted.
Training & Recruitment	145,931	Primarily due to the freeze on external recruitment and staff training taking place later in the year.
Conference & Project costs	65,098	Reduced project activity due to constraints on spend and resource available.
Post, Stationery & Printing	28,149	Printing of inspection and other reports budgeted for are no longer being carried out.
Legal	(29,580)	Additional costs because of advice required.
Consultancy	45,005	Less activity than planned to date, partially due to financial controls and resources available.
Accommodation	(18,423)	Relocation costs not budgeted for.
Non Cash Costs	50,031	Write off of Finlaison House improvements not budgeted for.
Capital charges	65,379	Change in accounting treatment of depreciation resulted in charges being different to profile.

1 () denotes an over-spend

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

Forecast outturn

17. As summarised in Annex A, year-end income is expected to be £336k (5.2%) less than budgeted over the year as a whole, due to changes in the numbers of establishments paying licence fees.

18. 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 **£649k** (10.2%). The forecast has reduced significantly from forecasts in previous reports following detailed review. At this stage, we can be clearer about staffing and likely expenditure in the remainder of the year. In particular, forecast expenditure on recruitment and salaries has reduced.

Other key performance indicators

Reserves

19. Total reserves at the end of December are £4.6m and our cash balance is £4m.

Debtors

20. As at 31 December our licence fee gross debtor balance was **£82k**. Fees were outstanding from 13 establishments. 74% is due from public sector bodies and 26% from private sector bodies (£60.5k public sector and £21.5k private sector).

21. All 13 establishments with outstanding fees have now been referred to our legal department. Payment is expected from two establishments by the end of January, three are being issued with legal proceedings, and the remainder are under review.

Prompt payment

22. For the nine months ended 31 December, 98.9% of invoices were paid within 30 days of receipt of a valid invoice, and 78.3% were paid within 10 days. The average payment time was 6.4 days. For the month of December 46.9% of invoices were paid within the 5 day target. The significant decrease, relative to the 73.4% reported for November, was due to staff absences over the Christmas period.

Financial risks

23. Financial risks that could arise in the future continue to be considered on an ongoing basis. Below is a table of the potential risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high level strategic risks that SMT have identified and are managing.

Risk	Link to the HTA's strategic risks	Mitigating actions and controls
A significant under-spend leading to a loss of stakeholder confidence in HTA's ability to manage resources effectively.	Inadequate relationship management	Regular monitoring of the annual budget by SMT and budget managers throughout the financial year with realistic forecasts of the likely outturn from as early as possible. Repayment of unused licence fees to establishments.
The HTA is required to	Insufficient financial	The HTA's financial

Risk	Link to the HTA's strategic risks	Mitigating actions and controls
undertake additional functions or activities not planned or costed within the approved budget.	resources Failure to manage change Inability to carry out its statutory remit	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.
The cost of the HTA's office relocation not all met by DH.	Failure to manage change	Costs are reflected in budget forecasts.
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.
Establishments change their profile resulting in a reduction in both hubs and satellites.	Failure to manage change	HTA undertake a periodic review of establishments and track changes to the number of hubs and satellites regularly. Budgets would then need to be managed or costs recovered through licence fees.

Conclusion

24. The Authority is asked to note the financial position as at 31 December 2010.

Human Tissue Authority

Summary - Income & Expenditure

Annex A

For the Nine Months Ending 31 December 2010

Year to Date			FULL YEAR			
Actuals	Budget	Variance	Forecast	Budget	Variance	%
£	£	£	£	£	£	%

INCOME & EXPENDITURE SUMMARY							
Income	(5,795,820)	(6,128,020)	332,200	(6,056,320)	(6,392,770)	336,450	-5.26%
Less:							
Expenditure	4,006,759	4,773,971	(767,212)	5,406,514	6,392,770	(986,257)	-15.43%
Gross (surplus)/deficit of income over expenditure	(1,789,061)	(1,354,049)	(435,012)	(649,806)	0	(649,807)	
Exceptional items							
Internal adjustments	(98,965)	0	(98,965)	(98,965)	0	(98,965)	
2006-2010 Rebate	728,952	0	728,952	1,143,000	0	1,143,000	
Total Exceptional Items	629,987	0	629,987	1,044,035	0	1,044,035	
Net (surplus)/deficit of income over expenditure	(1,159,074)	(1,354,049)	194,975	394,229	0	394,229	

Human Tissue Authority

ANNEX B

Member Income Summary

For the Nine Months Ending 31 December 2010

	Year to Date			FULL YEAR			
	Actuals £	Budget £	Variance £	Forecast £	Budget £	Variance £	%
Grant In Aid							
GIA	798,500	794,250	4,250	1,059,000	1,059,000	0	0.00%
Sub-Total	798,500	794,250	4,250	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	1,794,000	1,896,000	(102,000)	1,794,000	1,896,000	(102,000)	-5.38%
Public Display	25,870	42,930	(17,060)	25,870	42,930	(17,060)	-39.74%
Research	877,800	947,100	(69,300)	877,800	947,100	(69,300)	-7.32%
Human application	1,965,200	2,100,800	(135,600)	1,965,200	2,100,800	(135,600)	-6.45%
Sub-Total	4,896,545	5,234,480	(337,935)	4,896,545	5,234,480	(337,935)	-6.46%
Other							
Other income	554	0	554	554	0	554	#DIV/0!
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	5,795,820	6,128,020	(332,200)	6,056,320	6,392,770	(336,450)	-5.26%

Human Tissue Authority

Summary - Expenditure

Annex C

For the Nine Months Ending 31 December 2010

Year to Date			FULL YEAR			
Actuals	Budget	Variance	Forecast	Budget	Variance	
£	£	£	£	£	£	%

EXPENDITURE SUMMARY							
Staff Costs	2,398,052	2,817,232	(419,180)	3,117,417	3,747,066	(629,650)	-16.80%
Non Staff Costs	1,608,707	1,956,739	(348,033)	2,289,097	2,645,704	(356,607)	-13.48%
Gross Costs before Exceptional Items	4,006,759	4,773,971	(767,212)	5,406,514	6,392,770	(986,257)	-15.43%
Exceptional items							
Internal adjustments	(98,965)	0	(98,965)	(98,965)	0	(98,965)	
2006-2010 Rebate	728,952	0	728,952	1,143,000	0	1,143,000	
Total Exceptional Items	629,987	0	629,987	1,044,035	0	1,044,035	
Total Expenditure	4,636,746	4,773,971	(137,225)	6,450,549	6,392,770	57,779	0.90%

Human Tissue Authority

Directorate Summary

Annex D

For the Nine Months Ending 31 December 2010

	Year to Date				FULL YEAR			
	Actuals £	Budget £	Variance £	%	Forecast £	Budget £	Variance £	%
Communications	309,505	356,375	(46,870)	-13.15%	383,167	470,089	(86,922)	-18.49%
Regulation	783,135	951,836	(168,701)	-17.72%	991,726	1,274,756	(283,030)	-22.20%
Policy	753,765	997,747	(243,982)	-24.45%	980,203	1,338,868	(358,665)	-26.79%
HTA Board	125,750	195,894	(70,145)	-35.81%	181,237	277,859	(96,622)	-34.77%
Resources	1,669,697	1,785,402	(115,705)	-6.48%	2,362,337	2,395,359	(33,022)	-1.38%
Chief Executive's Office	364,908	486,717	(121,809)	-25.03%	507,843	635,840	(127,997)	-20.13%
Subtotal	4,006,759	4,773,971	(767,212)	-16.07%	5,406,514	6,392,770	(986,257)	-15.43%
Exceptional adjustments	(98,965)	0	(98,965)		(98,965)	0	(98,965)	
2006-2010 Rebate	728,952	0	728,952		1,143,000	0	1,143,000	
	629,987	0	629,987		1,044,035	0	1,044,035	
Total Directorate(s) Expenditure	4,636,746	4,773,971	(137,225)	-2.87%	6,450,549	6,392,770	57,779	0.90%

Authority paper

Date	25 January 2010	Paper reference	HTA (04/11)
Agenda item	8	Author	Craig Muir

Criteria for judging ALB review options

Background

1. The Authority held its first substantive discussion about the implications of the Department of Health's (DH) Arm's-Length Bodies (ALB) review at its awayday on 29 September 2010. There was agreement that the functions undertaken by the HTA are essential in ensuring the safe and ethical use of human tissue.
2. Whilst the ALB review proposed that the majority of the HTA's functions should transfer to the Care Quality Commission (CQC), some of these proposals were tentative (e.g. the transfer of human application functions to the Medicines and Healthcare products Regulatory Agency (MHRA)), and some contingent on other decisions (the Academy of Medical Sciences' (AMS) review of medical research regulation). In some cases no proposals were made (public display and organ donation functions). Since the publication of the review, the HTA has worked closely with the Department of Health and other stakeholders to explore a range of options for the transfer of functions.
3. At its meeting on 23 November, the Authority discussed a paper which described a number of different transfer options and what these might mean for the HTA's governance and management and which also set out stakeholder and staff views on those options. Authority Members requested a further paper on the criteria against which the merits of different options could be judged.

Purpose of the paper

4. This paper has two purposes:
 - (i) it proposes a set of criteria against which the HTA can assess any transfer proposals;
 - (ii) it sets out the case that, judged against these criteria, there is a strong argument for keeping the HTA's functions together in a single entity.

Action

5. The Authority is asked to note the criteria as a basis for assessing transfer options and to agree the assessment that the HTA's functions are best protected by keeping them together in a single entity.

Criteria for judging different options

6. The Authority believes, that, in any transfer of its functions, an organisational model should be adopted which is best able to maintain public and professional confidence in the safe and ethical use of human tissue. This would be achieved by meeting the following criteria.
7. **Criterion one:** *Clear focus* on the safe and ethical use of human tissue with proper, consistent, arrangements for *consent*, in the public interest.
8. **Criterion two:** *Light touch, proportionate* regulation which encourages *improvement in the standards, quality and effectiveness* of the sectors we regulate, and minimises the burden of regulation.
9. **Criterion three:** Provides *transparency* and clear *accountability* in the governance arrangements which ensure the safe and ethical use of human tissue.
10. **Criterion four:** Has *independence, expertise and credibility in representing the interests of the public* in the safe and ethical use of human tissue, in particular through lay and professional *non-executive input* and effective *networks* with relevant centres of expertise.
11. **Criterion five:** *Costs* of regulation are not increased, and are kept to a minimum.

Assessment

12. **Criterion one:** *Clear focus* on the safe and ethical use of donated human tissue with proper, consistent, arrangements for *consent*, in the public interest.
13. By clear focus, we mean that the issues and events that led to the HTA being established are given the dedicated attention they deserve in order to protect the public, in whose interests we regulate. By ethical, we mean predominantly that proper consent is given for the removal, storage or use of tissue for particular purposes. It is essential that any transfer does not undermine the work achieved by the HTA to date in ensuring that the individual's right to decide what happens to their body in life and death, or the bodies of their loved ones, is

paramount, and that 'appropriate and valid consent' is interpreted and applied consistently.

14. **Assessment:** We believe strongly that the criterion one is best served by keeping the HTA's function together in a single entity. This is because:

- While good progress has been made, there is still a job to do to ensure that consent is in place for the safe and ethical use of human tissue: the reasons behind the establishment of the HTA are still valid.
- Spreading the HTA's functions between different organisations risks there being no single body acting as the guardian of consent. This may result in different interpretations and standards of consent in different sectors over time.
- The ALB review makes no recommendations about the public display sector and our functions in relation to transplantation. As we believe consent is the golden thread which links all our activities, regardless of sectoral distinctions, we also believe that the best solution for these is to keep them together in a single entity. If our functions were spread amongst various organisations there would be no natural home for these "orphan" sectors.

15. While the Authority recognises that organisations representing sectoral interests will have views about what is the best regulatory approach for their sector (which in some cases may be splitting the HTA's functions), our overarching concern is with safeguarding consent which argues for keeping our functions together.

16. **Criterion two:** *Light touch, proportionate* regulation which promotes *improvement in the standards, quality and effectiveness* of the sectors we regulate, and minimises the burden of regulation.

17. By light touch and proportionate, we mean a style of regulation which does not impose unnecessary burdens on the establishments we regulate. It also means that new arrangements should not create new regulatory burdens as a result of dispersing the HTA's functions. Any new arrangements should not put at risk the improvements in standards, quality and effectiveness that the HTA has helped sectors to attain.

18. **Assessment:** We believe that criterion two is most likely to be achieved by keeping the HTA's functions together in a single entity. This is because:

- The HTA is recognised as being a light touch, proportionate regulator that adheres to the principles of better regulation.

- There is strong evidence from the sectors we regulate that the work of the HTA has had a direct impact in raising standards.
- Perhaps criterion two could be met if the HTA's functions were split, but we believe that we have achieved these by our regulatory approach and organisational culture. We therefore conclude that the risks to maintaining these benefits are greater if the functions are split, as the receiving bodies will have different regulatory approaches and cultures of their own. Splitting the functions also risks damage to the momentum which has built up to improve standards, and will potentially hamper future improvements.
- There are strong interrelationships between the sectors we regulate which argue persuasively for retaining a single unified regulator for human tissue. For example, if the consent process for taking samples at the post mortem stage is inadequate and public confidence declines, any resulting fall in the levels of donations may adversely affect research.
- Splitting our statutory functions between different bodies has the potential to create further burdens on licensed establishments if functions are split along sectoral lines. For example, an establishment which undertakes post mortems and stores tissue for research, and is currently licensed and inspected by the HTA, may, if functions are split, be licensed and inspected by two regulators.

19. **Criterion three:** Provides *transparency* and clear *accountability* in the governance arrangements which ensure the safe and ethical use of human tissue.

20. By this, we mean that it should be clear, to those we regulate and to the public, that there is one body responsible for making decisions in relation to the safe and ethical use of human tissue, what those decisions are and why they were made.

21. **Assessment:** We believe that criterion three is most likely to be achieved by keeping the HTA's function together in a single entity. This is because:

- The HTA currently acts as the sole guardian of consent in relation to human tissue and organs and has a variety of mechanisms by which it achieves transparency. For example, public Authority meetings, respected consultation mechanisms, and a strong track record of stakeholder communication.
- The HTA is accountable as the single body responsible for implementing the provisions of the Human Tissue Act. Splitting responsibility among a number of bodies will remove the single line of accountability for decisions regarding the safe and ethical use of human tissue. This may result in greater complexity and the scope for different interpretations of the Act's provisions, resulting in possible loss of public confidence.

- Other bodies, notably the CQC, will have many other concerns, many of which they may see as higher priority than HTA issues.

22. **Criterion four:** Has *independence, expertise and credibility in representing the interests of the public* in the safe and ethical use of human tissue, in particular through lay and professional *non-executive input* and effective *networks* with relevant centres of expertise.

23. We believe that the effective regulation of human tissue has been possible through the development of skills, experience and relationships which have been cultivated over time. These assets, which are critical, should be protected in any transfer of functions.

24. **Assessment:** We believe that criterion four is most likely to be achieved by keeping the HTA's function together in a single entity. This is because:

- Splitting the HTA's functions between a number of bodies runs a greater risk of diffusing and either losing, or greatly weakening, the intellectual and social capital that has been developed as a result of having the expertise under one roof.
- It would be difficult (and costly) to attempt to replicate this expertise in several different organisations.

25. **Criterion five:** Costs of regulation are not increased and are kept to a minimum.

26. **Assessment:** We believe that criterion five is most likely to be achieved by keeping the HTA's functions together in a single entity. This is because:

- The HTA is a small organisation of only 50 staff which is already delivering significant efficiency savings year on year, reducing licence fees for many establishments and rebating licence fees where we can.
- Some establishments which are currently licensed and inspected by the HTA may in future be regulated by more than one body if functions were split. Even though some establishments will be inspected by fewer organisations, there is currently no evidence that this will reduce licence fees.
- Splitting of the HTA's functions will be more complex than keeping them together, so the costs of delivering are likely to be greater.
- Replicating the necessary non-executive lay and professional expertise would be difficult and costly.

Authority paper

Date	25 January 2011	Paper reference	HTA (05/11)
Agenda item	9	Author	Caroline Browne Kara Firth Pravat Bhattachayra

Post mortem sector audit of retained material

Purpose of paper

1. To update the Authority about the audit of tissue retained by post mortem (PM) sector establishments. This audit was required to be completed via General Directions issued in April 2010.

Background

2. The General Directions were part of a programme of work aimed at addressing common areas of shortfalls at PM establishments in meeting HTA quality standards relating to consent, traceability and disposal. These areas were identified across the sector from site-visit inspections and incidents which were brought to the HTA's attention either voluntarily by establishments or through contact from a family or member of the media.
3. General Directions were issued to PM sector establishments on 30 April 2010, requiring establishments to carry out an audit of retained PM material, to be submitted to the HTA no later than 30 September 2010. The HTA consulted with representatives of the Royal College of Pathologists and the Association of Anatomical Pathology Technologists in determining the specifications of the audit. This ensured that the audit was reasonable and proportionate whilst giving the HTA the necessary assurances that establishments are meeting the consent requirements of the Human Tissue Act 2004 (HT Act).
4. The objectives of the audit of retained PM tissue were:

- to understand more about the nature and quantity of relevant material stored on licensed premises and the reason for its retention
- to identify where and why tissue may be being stored without appropriate consent
- to assure the HTA that licensed establishments have robust and reliable systems of traceability and records management, and identify those that do not in order that support can be provided to help them fully meet the HTA quality standards

Current position

5. A total of 202 establishments were required to complete the audit. Around 150 of these submitted their returns by the deadline of 30 September 2010 and a further 50 submitted returns in October and early November 2010. Two establishments have yet to submit returns and work is ongoing to resolve this issue.
6. The initial analysis of the audit returns identified 52 establishments where there were queries about the completeness, accuracy or clarity of the data in regard to the retention of organs, wet tissue and/or foetuses and fetal tissue. Further work is being done to resolve these issues and it is expected that the final audit report due for publication in March 2011 will be based on all or almost all establishments in the sector. At the present time, therefore, complete data is available for only around three-quarters of establishments and it is not yet appropriate to present an analysis of the information so far provided.
7. Early indications suggest that in a small number of establishments the reasons for retention of organs, wet tissue and/or foetuses and fetal tissue are not clear. The data from these establishments will be checked and, if it seems that there is a lack of clarity about retention, they will be asked to what extent they have been able to resolve their issues and are likely to be prioritised for an on-site inspection in the near future.
8. There were fewer problems with the completeness, accuracy or clarity of the data in regard to the traceability of the audit of blocks and slides. Early indications suggest that in around half of the establishments, all (100%) of the blocks and slides could be traced fully, and only in a small minority of establishments could less than 75% of the blocks and slides be traced fully. Further analysis of the data for blocks and slides will be presented in the final audit report.

Benefits of the audit

9. The HTA is very grateful for the support of the PM sector in completing the audit. A number of benefits will be achieved by the audit:

- For the first time accurate information about the nature and quantity of PM tissue being retained by all licensed establishments as well as the reasons for retention thus establishing a sound basis for public confidence
- a robust basis on which to develop guidance to the sector and for individual establishments, demonstrating that the HTA takes a reasonable, proportionate and supportive approach to regulation, which is based on evidence
- any potentially inappropriate retention of tissue has been identified and can be addressed with the support of the HTA
- tailored advice and guidance can be provided to individual establishments in order to improve systems relating to consent, traceability and disposal
- common areas of difficulty will inform HTA regulatory policy ensuring clarity about our expectations and consistency in the application of quality standards
- increased public confidence that tissue is not being retained or used for scheduled purposes where consent has not been given.

Next steps

- Further work to ensure the completeness and accuracy of data provided during the audit
- Further analysis of the audit data
- Discussions with stakeholders in the post mortem sector (via the Histopathology Working Group) about the findings of the audit and how they might best be used
- Publication of the audit report by 31 March 2011

Authority paper

Date	25 January 2011	Paper reference	HTA (06/11)
Agenda item	10	Author	Melanie Reid

Significant regulatory activity report - 1 October 2010 to 31 December 2010

1. This paper summarises the significant regulatory activity taken by the Human Tissue Authority (HTA) between 1 October 2010 and 31 December 2010.
2. Details of the regulatory enforcement action available to the HTA can be found in the Regulatory Enforcement Policy which is published on the HTA's website.

Changes to the significant regulatory activity report

3. In July 2010, it was proposed that the significant regulatory activity report (the report) be expanded to include information on the action taken following the reporting of serious adverse events and reactions (human application sector); serious untoward incidents (post mortem sector); and the outcomes of investigations conducted by the HTA following information received from a complainant, whistleblower or the media. This additional detail would enable the Executive to demonstrate trends or emerging issues throughout the business year, as well as action taken.
4. The Authority agreed with the proposed changes to the purpose and content of the report; two reports in the updated format have now been considered by the Authority (September and November 2010). During the November 2010 Authority meeting, Members commented that the report was now too detailed for full consideration by the Authority. Members proposed that the report should come to the Authority for information only, following a more detailed consideration by the Regulation Members Group (RMG).
5. The RMG has not met for some time as the HTA's regulatory activity is now operating in steady state. Most substantive regulatory issues relate to policy

matters and are discussed by the Policy Members Group. The existing proposal from Members would entail reconstituting the RMG for a single agenda item, arguably one which is an issue of predominantly operational concern.

6. The Authority is asked to consider a revised proposal that the detailed scrutiny of the Significant Regulatory Activity Report is undertaken by SMT and that the strategic issues raised are reported to the Authority. The Authority would continue to receive the full report for information.

Sectors regulated under the Human Tissue Act 2004 (post mortem, anatomy, research and public display)

Legal notices

7. No licences were suspended or revoked between 1 October 2010 and 31 December 2010.
8. No special directions were issued between 1 October 2010 and 31 December 2010.

Serious untoward incidents (SUIs)

9. 16 SUIs were reported in the post mortem sector between 1 October 2010 and 31 December 2010, compared to nine in Q2 and 12 in Q1.

Number of incidents	Category of incident	Detail
7	Any incident that may result in adverse publicity that may lead to damage in public confidence	1 x cross contamination of a body with an infectious disease closed 1 x complaint about treatment of a body following post mortem examination ongoing 2 x complaints about viewing the wrong body (1 x ongoing ; 1 x closed) 1 x memory card containing photographs of post mortem examinations lost ongoing 1 x deceased body retained in the Emergency Department without movement to the mortuary ongoing 1 x non-viable product of conception misplaced ongoing
3	Discovery of an organ or tissue following post mortem examination and release of body	1 x error in paperwork falsely indicating no organs removed ongoing 1 x tissue removed without consent ongoing 1 x tissue inadvertently retained for 6 months following PME ongoing
2	Accidental damage to a body before or after PME	1 x minor, unexplained damage to the deceased's face ongoing 1 x complaint following a post-mortem injury to a body closed
2	Post-mortem examination (PME) conducted was not in line with the consent given or the PME proceeded without adequate consent	1 x full PME conducted where consent for a limited PME only was obtained ongoing 1 x PME conducted on a body due to confusion with paperwork ongoing
2	Release of the wrong body	2 x bodies accidentally released due to insufficient identity checks – in both cases, body returned safely to mortuary/funeral director (1 x ongoing ; 1 x closed)

Table 1: Numbers of serious untoward incidents in the PM sector reported to the HTA

Update on ongoing SUIs from previous quarters

10. The Q2 report documented nine reported SUIs in the PM sector. Subsequent to the Authority reviewing the report, one of the nine SUIs was reassessed and determined to not be an HTA SUI (relating to a body which was failed to be provided to an anatomy school in line with the deceased person's donation request).
11. Two SUIs reported in the Q2 report are still ongoing pending the submission of each establishment's internal investigation report.
12. No other SUIs from previous quarters are ongoing.

Allegations and other concerns raised with the HTA

13. Other than concerns addressed through the SUI reporting system, there were no allegations or concerns brought to the attention of the HTA between 1 October 2010 and 31 December 2010.

Representations and Appeals

14. There were no representations hearings or appeals committees held between 1 October 2010 and 31 December 2010.

Sectors regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007

Legal notices

15. No licences were suspended or revoked between 1 October 2010 and 31 December 2010.
16. Two sets of special directions were issued to establishments between 1 October 2010 and 31 December 2010:
- Directions were issued following a site-visit inspection of a newly licensed establishment. The directions restricted certain licensed activities from commencing until the establishment met the required standards, to be determined through a re-inspection.
 - Directions were issued as part of a proposal to grant a licence. The directions restricted certain licensed activities from commencing until the establishment was inspected by the HTA and found to meet the required standards.

Serious adverse events and serious adverse reactions (SAEARs) submitted between 1 October and 31 December 2010

Serious adverse events

No SAEs	Type	Date of incident	Description	Outcome
1	Distribution	17/12/10	Near miss – incorrect tissues and cells for a matched patient were received but not initially identified	Ongoing
1	End use	01/01/10	HTA received allegation of tissues and cells being inappropriately applied at the point of end use	Ongoing
1	End use	24/11/10	Erroneous expiry date allocated to a unit of tissues/cells indicated it could not be used	Tissues/cells disposed of closed
2	End use	11/11/10 11/11/10	Tissues/cells rejected at the point of end use	2 x ongoing
1	End use	15/12/10	Tissues/cells problematic at the point of end use	Tissues and cells transplanted closed
1	End use	15/12/10	Tissues/cells container found to be compromised prior to end use	Ongoing
1	End use	23/12/10	Tissues/cells transplanted before microbial testing results received; tests later indicated a positive result	Ongoing

No SAEs	Type	Date of incident	Description	Outcome
1	Processing	14/10/10	Delay in imported tissue leaving the country of origin caused it to be unsuitable for processing or storage	Tissues and cells were disposed of closed
3	Procurement	17/09/10 17/12/10 01/12/10	Unlicensed procurement	1 x closed 2 x ongoing
1	Procurement	28/08/10	Near miss – inappropriate pre-procurement procedures followed, causing a delay to procurement	Workload re-distributed to ensure sufficient numbers of trained staff available for procedure closed
1	Procurement	25/11/10	Inappropriate procurement procedures followed, increasing the risk of a serious adverse reaction in the donor	No serious adverse reaction reported. Staff member involved re-trained ongoing
2	Storage	28/06/10 14/10/10	Tissue packaging found to be inappropriately used by staff, compromising the sterility of the tissues	Procedures updated and staff re-trained 2 x closed
1	Storage	27/04/10	Freezer failure led to loss of non-matched tissue	Procedures updated closed
1	Storage	12/10/10	Freezer decommissioned without removal of all tissues/cells leading to loss of valuable relevant material stored on behalf of another establishment	Ongoing
1	Storage	15/11/10	Freezer failure during initial freezing process, leading to tissues/cells being maintained at an inappropriate temperature for 30 min	Ongoing
1	Testing	12/10/10	Microbial growth identified on testing plates subsequent to the release of tissue for end use	Tissue was not transplanted, investigation demonstrated a false positive result caused by environmental contamination closed

Serious adverse reactions

No SARs	Type	Date of incident	Description	Outcome
2	Graft failure	21/09/10 31/08/10	Graft failure of transplanted tissues/cells	2 x closed
2	Donor reaction	18/10/10 23/11/10	Donor experiencing pain 5 days after donation Femoral artery punctured during procurement	2 x Ongoing
1	Recipient reaction	22/09/20	Recipient experienced acute myocardial infarction following transplant of tissues/cells	Recovered in hospital ongoing

Update on ongoing SAEARs from previous quarters

17. One SAEAR from previous quarters remains open (reported to the Authority in Q2). The storage unit at a licensed establishment failed, resulting in the disposal of a significant amount of tissue for treatment. The SAE was examined as part of a recent routine site-visit inspection, which indicated failure of governance processes at the licensed establishment. The establishment have voluntarily ceased licensable activities while the internal investigation is undertaken and the SAE will remain open until details of the follow up action are received and assessed by the Executive.

Reporting requirements

18. In October 2010, the HTA introduced a requirement for establishments in the human application sector to report initial notifications of SAEARs to the HTA within 24 hours of being identified.
19. In Q2 2010/11, the average initial reporting time for SAEARs was 34 days. Following the introduction of the 24-hour reporting requirement, the average initial reporting time has dropped by 55% to 15 days. Although a significant improvement, this remains longer than the policy target of reporting within 24 hours.
20. Whilst it is recognised that this change in policy may take some months to become embedded in the sector, the Executive staff are taking this requirement seriously and regularly communicating the policy to staff at licensed establishments e.g. during inspections, via the website, via the e-newsletter and during the recent Human Application sector conference. The Executive will continue to monitor the reporting times for SAEARs and report this back to the Authority at regular intervals.

Allegations and other concerns raised with the HTA

21. Two allegations/concerns were raised with the HTA about two establishments in the human application sector between 1 October 2010 and 31 December 2010:
 - The Portuguese Competent Authority (CA) contacted the HTA regarding a UK-based licensed establishment who has agreements in place for activities to be carried out in Portugal on their behalf. The CA alleged that the activities carried out in their country did not meet the required standards for safety and quality. The Executive provided the CA with information about the UK-based licensed establishment to assist them with their investigations into the Portuguese activities.

- A Designated Individual from a HTA-licensed establishment alleged that licensable activities may be occurring at an unlicensed establishment. The Executive investigated and determined the allegations to be unfounded.

Representations and Appeals

22. No representations hearings or appeals committees were held between 1 October 2010 and 31 December 2010.

Conclusion

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

Appendix 1: Summary of outcomes 2010/11 for establishments regulated under the Human Tissue Act 2004					
Description	How the HTA was notified of the issue	Significant regulatory action taken	Authority Paper	Outcome	Length of time taken to resolve
Legal notices					
Q1: General Directions issued to all post mortem sector establishments to complete updated compliance information and conduct an audit of retained material	N/A	None		All post mortem sector establishments have reported compliance information. Two establishments have not yet submitted audit results.	

Serious untoward incidents					
<p>Release of the wrong body</p> <ul style="list-style-type: none"> • Q1: 4 incidents reported • Q2: 0 incidents reported • Q3: 2 incidents reported 	Voluntarily reported	None	<p>Q1: Sept 10 Q3: Jan 11</p>	<p>Q1: 4 x closed. Investigations concluded and appropriate improvement measures are in place</p> <p>Q3: 1 x ongoing. 1 x closed. Procedures updated and staff re-trained.</p>	
<p>Accidental damage to a body before or after post-mortem examination</p> <ul style="list-style-type: none"> • Q1: 3 incidents reported • Q2: 1 incident reported • Q3: 2 incidents reported 	Voluntarily reported	None	<p>Q1: Sept 10 Q2: Nov 10 Q3: Jan 11</p>	<p>Q1: 3 x closed. New procedures introduced and staff retrained</p> <p>Q2: 1 x closed. Investigations concluded and appropriate improvement measures are in place</p> <p>Q3: 1 x ongoing, 1 x closed. Incidents discussed with staff/staff re-trained.</p>	

<p>Loss of an organ</p> <ul style="list-style-type: none"> • Q1: 1 incident reported • Q2: 0 incidents reported • Q3: 0 incidents reported 	<p>Voluntarily reported</p>	<p>None</p>	<p>Q1: Sept 10</p>	<p>Q1: closed. Premises and systems have been improved to reduce risk of recurrence.</p>	
<p>Serious security breach</p> <ul style="list-style-type: none"> • Q1: 1 incident reported • Q2: 0 incidents reported • Q3: 0 incidents reported 	<p>Voluntarily reported</p>	<p>None</p>	<p>Q1: Sept 10</p>	<p>Q1: closed. Security assessed. Improved procedures introduced and new safe installed.</p>	
<p>Any incident that could result in adverse publicity that may lead to damage in public confidence.</p> <ul style="list-style-type: none"> • Q1: 1 incident reported • Q2: 2 incidents reported • Q3: 7 incidents reported 	<p>Voluntarily reported</p>	<p>None</p>	<p>Q1: Sept 10 Q2: Nov 10 Q3: Jan 11</p>	<p>Q1: closed. Retraining given to staff about delivery of body parts. Q2: 2 x closed. Procedures updated and staff retrained. Q3: 5 x ongoing. 2 x closed. Issues discussed with relevant staff/procedures updated to reflect improved practice.</p>	

<p>Discovery of an organ or tissue following post mortem examination and release of body</p> <ul style="list-style-type: none"> • Q1: 0 incidents reported • Q2: 3 incidents reported • Q3: 3 incidents reported 	Voluntarily reported	None	Q2: Nov 10 Q3: Jan 11	Q2: 2 x closed . Procedures updated and staff re-trained. 1 x ongoing Q3: 3 x ongoing	
<p>Incident leading to the temporary unplanned closure of a mortuary resulting in an inability to deliver services</p> <ul style="list-style-type: none"> • Q1: 0 incidents reported • Q2: 1 incident reported • Q3: 0 incidents reported 	Voluntarily reported	None	Q2: Nov 10	Q2: ongoing	
<p>Post mortem examination of the wrong body</p> <ul style="list-style-type: none"> • Q1: 0 incidents reported • Q2: 1 incident reported • Q3: 0 incidents reported 	Voluntarily reported	None	Q2: Nov 10	Q2: closed . Procedures updated and staff re-trained.	
<p>Post-mortem examination conducted was not in line with the consent given or the PME proceeded without adequate consent</p> <ul style="list-style-type: none"> • Q1: 0 incidents reported • Q2: 0 incident reported • Q3: 2 incidents reported 	Voluntarily reported	None	Q3: Jan 11	Q3: 2 x ongoing	

Complaints and other concerns raised with the HTA					
Q1: A family member contacted the HTA raising concerns about the cremation of a body part when a request was made for it to be returned for the family to arrange the cremation.	Voluntarily reported	HTA worked with the establishment to undertake a full investigation.	N/A	HTA standards not breached. Advice given to help improve communication flows between the analytical laboratory and Coroner Closed.	8 June 2010 – Final communication issued 28 July 2010.
Q2: Staff from a licensed anatomy establishment contacted the HTA to advise that they had found an external fixed brain specimen on their premises	Voluntarily reported	None	N/A	HTA standards not breached. Establishment referred the matter to the police as well as conducted an investigation. Closed.	1 July 2010 - 9 July 2010
Representations and appeals					
None					

Appendix 2: Summary of outcomes 2010/11 for establishments regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007					
Description	How the HTA was notified of the issue	Significant regulatory action taken	Authority Paper	Outcome	Length of time taken to resolve <i>(notification date – final outcome)</i>
Legal notices					
Q1: A notice of suspension was issued when a company went into liquidation and the licence holder was unable to nominate a suitable Designated Individual (DI) to supervise licensable activities.	Change of DI form submitted to HTA and DI found unsuitable.	Advice and guidance, licence suspended and licence revoked.	September	Tissues and cells were no longer stored on site. This licence has now been revoked. Closed.	15 January 2010 – 25 May 2010 (128 days)

<p>Q1: Special directions were issued to three establishments which prevented the issue of any samples for end use prior to the HTA being assured about the suitability of the premises.</p>	<p>Site-visit inspection</p>	<p>Special directions issued. Follow up inspection with experts in attendance.</p>	<p>September</p>	<p>Premises considered suitable with licence conditions and advice and guidance issued to improve monitoring of the premises. Closed</p>	<p>Inspections 17/18 March & 9 April 2010. Final report issued 22 June 2010</p>
<p>Q2: Four sets of special directions were issued to revoke previously issued directions to indefinitely hold tissues or cells.</p>	<p>1 x request from licensed establishments to enable disposal. 3 x once the suitability of processing premises was assured (see above) and the establishment's representations were heard</p>	<p>None</p>	<p>N/A</p>	<p>1 x establishment disposed of unsafe tissues and cells being held 3 x establishments able to release material for end use Closed</p>	<p>6 August 2010 – 26 August 2010 Representation Panel determination issued 26 August 2010. Directions revoked 7 October 2010</p>

Q3: Two sets of special directions were issued to two establishments to restrict each from undertaking licensable activities until the HTA was satisfied standards were being met	1 x new licence application (for change of premises) 1 x site-visit inspection	Special directions issued		2 x licensable activities described in the directions have not yet commenced	Pending
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Serious adverse events and serious adverse reactions					
Procurement <ul style="list-style-type: none"> • Q1: 1 procurement SAE • Q2: 6 procurement SAEs • Q3: 5 procurement SAEs 	Voluntarily reported		Q1: Sept 10 Q2: Nov 10 Q3: Jan 11	Q1: closed Q2: 6 x closed Q3: 2 x closed , 3 x ongoing	
Processing <ul style="list-style-type: none"> • Q1: 1 processing SAE • Q2: 2 processing SAEs • Q3: 1 processing SAE 	Voluntarily reported		Q1: Sept 10 Q2: Nov 10 Q3: Jan 11	Q1: closed Q2: 2 x closed Q3: 1 x closed	
Testing <ul style="list-style-type: none"> • Q1: 0 testing SAEs • Q2: 1 testing SAE • Q3: 1 testing SAE 	Voluntarily reported		Q2: Nov 10 Q3: Jan 11	Q2: closed Q3: closed	
Storage <ul style="list-style-type: none"> • Q1: 5 storage SAEs • Q2: 6 storage SAEs • Q3: 5 storage SAEs 	Voluntarily reported		Q1: Sept 10 Q2: Nov 10 Q3: Jan 11	Q1: 4x closed Q2: 6 x closed Q3: 3 x closed , 2 x ongoing	
Distribution <ul style="list-style-type: none"> • Q1: 1 distribution SAE • Q2: 5 distribution SAEs • Q3: 1 distribution SAE 	Voluntarily reported		Q1: Sept 10 Q2: Nov 10 Q3: Jan 11	Q1: closed Q2: 5 x closed Q3: ongoing	

<p>End use</p> <ul style="list-style-type: none"> • Q1: 0 end use SAEs • Q2: 4 end use SAEs • Q3: 7 end use SAEs 	Voluntarily reported		<p>Q2: Nov 10</p> <p>Q3: Jan 11</p>	<p>Q2: 4 x closed</p> <p>Q3: 5 x ongoing, 2 x closed</p>	
<p>Q1: Errors led to tissue being released for human application which had positive results for microbiological testing.</p>	Voluntarily reported		Q1: Sept 10	Q1: closed	
<p>Q1: Administrative errors led to errors in record keeping.</p>	Voluntarily reported		Q1: Sept 10	Q1: No serious adverse reactions in patient. Closed	
<p>Computer programming error led to misreporting of donors' wishes</p> <p>Q1: 21 SAEs</p>	Voluntarily reported	<p>Advice and guidance given. Extensive feedback and comprehensive follow up action taken by establishment.</p>	Q1: Sept 10	Q1: closed	
<p>Q1: Tissue damaged prior to end use.</p>	Voluntarily reported		Q1: Sept 10	Q1: No serious adverse reactions in patient. Closed	

<p>Q1: 9 serious adverse reactions:</p> <ul style="list-style-type: none"> • 1 fungal infection • 1 immunological reaction • 2 prolonged hospital stay • 1 anaphylactic reaction • 3 graft failure • 1 graft rejection 	<p>Voluntarily reported</p>		<p>Q1: Sept 10</p>	<p>Q1: 3 x closed, 6 x closed</p>	
<p>Q2: 6 serious adverse reactions:</p> <ul style="list-style-type: none"> • 4 x graft failure • Post operative infection • Donation cancelled but donor exposed to unnecessary administration of pre-donation treatment 	<p>Voluntarily reported</p>		<p>Q2: Nov 10</p>	<p>Q2: 2 x ongoing, 4 x closed</p>	
<p>Q3: 5 serious adverse reactions:</p> <ul style="list-style-type: none"> • 2 x graft failure • 2 x donor experiencing pain/injury • 1 x post transplant acute myocardial infarction 	<p>Voluntarily reported</p>		<p>Q3: Jan 11</p>	<p>Q3: 2 x closed, 3 x ongoing</p>	

Complaints and other concerns raised with the HTA					
Q1: An individual contacted the HTA raising concerns about the suitability of practices carried out by a licensed establishment which covered matters relating to several HTA standards.	Voluntarily reported	Expert advice has been sought.		Ongoing	
Q1: A complaint was received from a patient about a third party working under the direction of a HTA licence holder. The HTA has conducted an inspection site visit of the relevant third party premises. Concerns were raised about the control has over the activities of third parties.	Complaint letter	Two site-visits have now been carried out and learning incorporated into a new Guidance Document.		Closed	27 April 2010 – 6 September 2010
Q3: An EU competent authority raised concerns about an HTA licensed establishment. The HTA has provided the CA with information about the licensed establishment's activities in the UK.	Complaint letter	Provision of information to the CA		Closed	8 September 2010 – 18 November 2010

<p>Q3: A DI alleged that licensable activities may be occurring on unlicensed premises.</p>	<p>Telephone call</p>	<p>HTA contacted the unlicensed establishment and determined that no licensable activities were being carried out</p>		<p>Closed</p>	<p>2 December 2010 – 7 December 2010</p>
<p>Representations and appeals</p>					
<p>Q2: A DI made representations against nine additional conditions proposed to be added to a licence following a routine site-visit inspection.</p>	<p>DI issued notice of intention to make representations</p>	<p>N/A</p>	<p>Nov 10</p>	<p>Three proposed conditions were assessed as met prior to the Representations hearing. The Representations panel determined that two proposed conditions would not be applied to the licence, the remainder to be applied in a modified form</p>	<p>Notice of intention received 12 July 2010. Representations Hearing on 23 August 2010 (42 days)</p>



Authority paper

Date	25 January 2011	Paper reference	HTA (07/11)
Agenda item	11	Author	Kate Rolfvondenbaumen

Summary of post-inspection feedback for 2010

Purpose

1. This paper is intended to provide the Authority with a review of the inspection feedback that has been collected from establishments inspected between 1 January 2010 and 31 December 2010.

Recommendation

2. The Authority is asked to continue its support of this initiative and any changes made at the operational level that may further increase both the quality and quantity of post inspection feedback from establishments.
3. The Authority is asked to continue its support of the uses outlined in paragraph seven.

Background

4. The 2009/2010 business plan included an objective for the Human Tissue Authority and particularly the Regulation Directorate to build and develop effective relationships with stakeholders and the public, based on trust, and to capture and evaluate stakeholder opinion.
5. One of the methods used by the Regulation Directorate to satisfy this objective is the collection and evaluation of feedback from site-visit inspections.
6. The Regulation Directorate provides all individuals from establishments who have been involved in an HTA site-visit inspection with the opportunity to provide feedback on their experience.

7. A new feedback form and method of collection was introduced in 2009. This has resulted in a 20% increase in the number of establishments providing feedback (the rate of return has increased from ~ 30% to ~ 50%).
8. Information gathered is:
 - directly fed back to the lead/support inspector for personal development
 - sent to the line manager (a Head of Regulation) to feed into the Performance Development Plan (PDP) process
 - shared with the Regulation Directorate at regular intervals
 - reported to the Authority as an indicator of performance
 - used to identify areas where HTA's inspection processes or procedures could be improved
 - used to inform training for Regulation staff.

Methods & Results

9. 193 inspections were carried out during the defined period (see Appendix 1). The breakdown according to sector is set out below:
 - Human Application = 99
 - Post Mortem = 65
 - Research = 22
 - Anatomy = 4
 - Public Display = 3
10. Feedback forms (see Appendix 2) are distributed at the end of each inspection by the lead inspector. Regulation Managers have been provided with a speaking note that outlines the reason feedback is collected and how it is used.
11. All members of staff who participated in the inspections are encouraged to complete a feedback form. Completed forms are returned to a Regulation Assistant who records all responses in an excel spreadsheet.
12. 51% of the establishments inspected provided feedback. Feedback was received from all sectors with the exception of public display. The greatest percentage of feedback came from the research sector; the lowest from the post mortem sector.
13. Overall, the respondents demonstrated a very high level of satisfaction with HTA inspectors and the HTA inspection process with over 95% of respondents rating the inspection process as either 'good' or 'excellent'. This represents an improvement from previous report of November 2009 where 87% of the respondents rated the process as 'good' or excellent'.

14. Questions 3-6 on the feedback form had high scores and establishments provided positive comments. Examples of written feedback include:

- process was very helpful with excellent advice from the inspectors
- very positive experience; encourages further engagement
- a good, in-depth, inspection that fully covered the HTA remit; keep the level/approach like the current process.

15. Where lower levels of satisfaction with the inspection process were identified these have been brought to the attention of the Heads of Regulation. Lower scores were limited to questions concerning the inspection scheduling and timetable, and represented less than 3% of all establishments providing feedback; the written comments indicated that establishments find changes to inspection teams to be unnerving and frustrating, and certain times of the year (e.g. school holiday periods) to be less than ideal for an inspection to take place. Examples of comments include:

- changes in the last few weeks were surprising
- August was not the best time to carry out an inspection due to the absence of some key staff on holiday
- request for detailed information in the preceding 2 weeks was a little 'last minute'
- change in inspector did result in requests for information already supplied.

16. Response rates during the period have remained constant and are well within the expected range. However, we are keen to improve them and one suggestion under consideration is having the lead inspector send a reminder email (with an electronic copy of the feedback form attached) within three days of the inspection. The option to submit an electronic form may provide a further increase in the return rate.

17. Many respondents took the opportunity to provide more information in the final comments section; these comments highlighted three areas where our processes or practices could be strengthened or improved:

- providing a forum to capture best practice that can be accessed by all establishments
- providing training for establishments on the inspection process (this comment was repeated by a number of research establishments)
- continuing (and increasing) the number of joint inspections - these reduce the preparatory burden for establishments and provide an excellent opportunity to engage with regulators at the same time.

18. Comments made by establishments are being addressed through the process review and development of the business plan for 2011/2012.

Conclusions

19. The current system of capturing feedback post-inspection provides the opportunity for the Regulation Directorate to develop and strengthen relationships with stakeholders by providing them with the opportunity to feed into our continuous improvement strategy.
20. The project has the additional benefit of providing Regulation Managers with immediate and valuable individual feedback on their approach to inspections, which can lead to further personal and professional development.

Next Steps

21. Effective as of 1 February 2011, lead inspectors will send out an electronic copy of the post inspection feedback form with a prompt to encourage a response.
22. The Regulation Directorate will use the feedback to review processes and, where appropriate, actions will be incorporated into the 2011/2012 business plan.

Appendix 1

Questionnaires returned

Sector	No. of Inspections	No. of establishments providing feedback	% of forms returned
Human application	99	54	55%
Post mortem	65	30	46%
Research	22	13	59%
Public display	3	0%	0%
Anatomy	4	2	50%
Total	193	99	51%

Appendix 2

Inspection Feedback Form

Your feedback is very important to us. Feedback from our inspections is carefully reviewed and the information provided is used to improve the quality of our inspection process.

This feedback will also be used to produce bi-annual reports for Authority Board members that will include a summary of the findings and recommendations for improvements. All information contained within these reports will be anonymised.

We would be grateful if you would take a few minutes to provide us with your feedback on your recent inspection.

Please send your completed questionnaire to:

Human Tissue Authority
151 Buckingham Palace Road
Victoria
London
SW1W 9SZ
Email: licensing.enquiries@hta.gov.uk

Please give a score of 1 – 4 for the first six questions:

1= Poor, 2= Average, 3= Good, 4= Excellent

If your rating is 2 or below please provide an explanation

1) Please rate the notification period and advance communications provided to you (e.g. was there sufficient time and information to prepare for the inspection?).

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

2 Please rate the timetable developed by the lead inspector (e.g. did it take into consideration the size of your establishment and level of activity)

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

3) Please rate the approach used by the inspection team (e.g. was it open and transparent, was the advice and guidance useful?).

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

**4) If you were interviewed, please rate your experience.
(Please circle one option: lead inspector, support inspector, uncertain)**

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

5) Please rate the information presented in the feedback meeting (e.g. did it provide you with a clear understanding of the inspection findings?).

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

6) Please rate the overall inspection process

1= Poor 2= Average 3= Good 4= Excellent

Comments (please feel free to elaborate on your rating above by providing some further information)

7) Please provide us with any other comments you may have on the inspection process or suggestions for improvements.

Your details

Licence number _____ Date of inspection _____

If you are happy for your feedback to be identifiable, please complete the following details:

Name _____ Job title _____

Organisation _____



Authority paper

Date	25 January 2011	Paper Reference	HTA (08/11)
Agenda item	12	Authors	Vicky Marshment

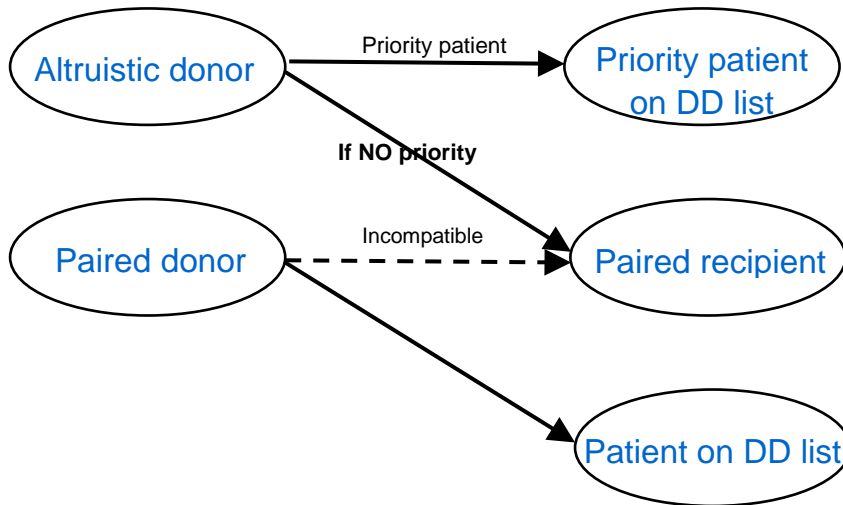
Domino paired living organ donations

Purpose

1. This paper defines domino paired organ donation, it also gives an indicative timeframe for the introduction of this novel form of donation in the UK.
2. The paper also aims to support discussion of whether the decision making in domino paired donations should be undertaken by a panel of Authority Members, or whether it should be delegated to the Executive.

Background

3. NHS Blood and Transplant (NHSBT) first contacted the HTA in June 2009 to explore the possibility of starting a domino paired organ donation scheme in the UK.
4. Domino paired organ donation involves a non-directed altruistic donor's kidney starting a chain of transplants for incompatible donors and recipients, with the remaining kidney being allocated to the deceased waiting list, as shown below.



NB: DD stands for deceased donor

Diagram courtesy of NHSBT

5. This is an established process in the US, with the most significant chain being of 12 transplants in seven different centres.
6. NHSBT hope to start a domino paired scheme in the UK in February 2011.

Assessment of domino paired donations

7. Legal advice has been sought as to whether domino paired donations require consideration by a panel of Authority Members under the Transplant Regulations.¹
8. It was advised that as Regulation 12 contains such tightly drafted definitions of paired, pooled and non-directed altruistic donations, domino paired donations do not fall within this Regulation.
9. This means that these cases do not have to be assessed by a panel of Authority Members. However the Authority may decide to retain decision-making in these cases, rather than delegate it to the Executive.
10. The decision by the Authority in 2006 not to delegate decision-making in cases of adult-to-adult liver donation was made on the basis of the relatively high risk such transplants carry, 1:200 risk of death. Domino paired donations do not carry an increased mortality risk.

¹ The Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006

11. The decision by Parliament to require Authority consideration of paired, pooled and non-directed altruistic cases was based on the novelty of these types of transplantation. Domino paired donations are novel forms of transplantation (in the UK).
12. The Authority decided in 2005 that all non-directed altruistic donors should undergo a psychiatric/psychological assessment prior to donation to ensure they are competent to consent.

Recommendation

13. Due to the novelty of domino paired donations it is recommended that the Authority retain the decision-making in these cases.
14. It is also recommended that the altruistic donor within the domino paired process undergoes a psychiatric/psychological assessment, as is the case for all other non-directed altruistic donors.
15. Finally, it is recommended that the HTA's process for the assessment of domino paired donations is reviewed by the Authority annually.

Operational issues and next steps

16. To ensure informed consent, the altruistic donor within the domino paired case will be made aware they will be the "trigger" for this process.
17. NHSBT will inform the HTA of the domino paired group and we will refer the cases together, to a single panel.
18. Initially, NHSBT will only be operating domino paired donation involving one pair (as per the diagram above), however they hope once this process is established to extend domino paired donation chains to involve more donor/recipient pairs.
19. The Executive will draft an update note to Independent Assessors (IAs) to advise them of the introduction of this type of donation, and also of the HTA's requirements and any special considerations to consider when assessing these cases.
20. A note will also be sent to all Living Donor Coordinators to make them aware of the information required in the referral letter for domino paired cases.

21. An update will be made to the Online Submission System to allow these cases to be easily identified and accurately labelled.

Authority paper

Date	25 January 2010	Paper Reference	HTA (09/11)
Agenda item	13	Author	Fidelma Murphy

HTA policy on composite tissue

Purpose

1. The purpose of this briefing is to update the Authority on the position taken by the Human Tissue Authority (HTA) regarding the regulation of composite tissue transplantation. The reason for this update is that this high-profile field of transplantation is developing rapidly, with the imminent likelihood of transplantation of a facial or limb graft happening in the UK. It is therefore important that the Authority Members are kept informed of our current position on this subject.

Context

2. The paper attached in the annex was presented to SMT and the recommendations were agreed as HTA policy. SMT agreed that a proportionate and risk based decision was that composite tissues are considered organs, which means that they are regulated under the consent provisions of the HT Act and, in the future, the Organ Donation Directive.
3. Since the completion of the HTA policy, and agreement from SMT, the final Directive 2010/45/EU of the European Parliament on standards of quality and safety of human organs intended for transplantation has been published, in which an organ has been defined as;

“organ” means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

4. This definition supports the decision made by the HTA earlier this year to consider composite tissues as organs where the tissues maintain structure, vascularisation and a capacity to develop physiological functions.

Next steps

5. A meeting is being arranged for early in 2011 to discuss with key stakeholders what composite tissues should be included in the definition of an organ. Following this meeting, it is planned that a comprehensive list will be compiled and communicated.

Annex

The regulation of composite tissue transplantation.

Purpose

1. The purpose of this paper is to recommend Human Tissues Authority's position on composite tissue transplantation and how it should be regulated.

Recommendation

2. It is recommended that the activity of composite tissue transplantation should not be regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Composite tissues are considered organs, which mean that they are regulated under the consent provisions of the Human Tissue Act 2004 (HT Act) and, in the future, the Organ Donation Directive (ODD). This would be an interim decision whilst we await the final draft of the ODD (see post script at paragraph 23).

Background and Context

Why is a policy required?

3. In July 2009, following a communication from the Royal Free NHS Foundation Trust, the Human Tissue Authority (HTA) initiated internal exploratory talks regarding the transplant of face, limbs, larynx, trachea, oesophagus, uterus and any other body parts that may not clearly fall within the definition of either an organ or a tissue. Professor Peter Butler at the Royal Free had raised a specific query about whether a face can be considered an organ. An interim decision was given that the Royal Free should proceed on the basis that their imminent face transplant be carried out on the same basis as if it were a solid organ, under the HT Act with appropriate consent provisions in place.
4. To help inform the writing of this paper, a meeting was arranged with Professor Butler. He provided information on some of the technical aspects of facial tissue transplantation, recent data on the international status of composite tissue transplantation, and information on the status of the Facial Tissue Transplantation Team at the Royal Free Hospital regarding their readiness to proceed with a facial transplantation.
5. This paper focuses on composite tissue grafts removed from deceased donors.

Definitions

A number of definitions are relevant to this paper:

6. **Organ** means a differentiated and vital part of the human body, formed by different tissues, that maintains its structure, vascularisation and capacity to develop physiological functions with an important level of autonomy. (European Union Tissue and Cells Directive [2004/23/EC]; Human Tissue Act 2004). This definition is also used in the Human Tissue Act 2004 (Persons who Lack Capacity to consent and transplant) Regulations 2006.
7. **Tissue** – a collection of cells specialised to perform a particular function. The cells may be of the same type or of different types. Aggregations of tissues constitute organs. (Concise Oxford Medical Dictionary, Fourth Edition).
8. **Composite tissue** – is multiple tissue or an amalgamation or fusion of tissue specialised to perform particular function or functions. Skin makes up the central element of many composite tissues. (Definition of word 'composite' from Concise Oxford Medical Dictionary, Fourth Edition)
9. **Transplantation** – means the process of restoring certain functions of the human body by transferring equivalent organs to a recipient (Draft Organ Donation Directive).
10. For the purpose of this paper, the case of facial tissue grafts will be used as an example of composite tissue to simplify discussion.
11. In February 2010, the HTA provided comments to the Department of Health (DH) on the proposed definition of an organ for the ODD. The paper backed the proposal from the European Unions Rapporteur's report that the word 'vital' should be removed from the definition of an organ along with other changes to include a part of an organ. This proposal would bring composite tissue within the remit of the ODD.
12. The DH was also asked to consider the issues relating to the skin and bone marrow, which is procured at the same time as the facial tissue to support the transplant.
13. Including composite tissue grafts within the definition of an organ would provide greater clarity and certainty for medical professionals involved in organ transplantation, as they would be following the same set of regulations.

Discussion

Procedure for facial transplantation.

14. Facial transplantation differs from the normal methods of facial reconstruction, which involve autologous tissue. The retrieval and management of a facial tissue graft, pending transplant, follows the same procedures as for a solid organ, including a very short procurement time (4-5 hours) following ischaemic death. The facial tissue graft has to be transplanted immediately. In terms of blood supply and vascularisation requirements, facial tissue grafts are much closer to solid organs than tissue; this includes the need to perfuse the grafts following retrieval. Patients receiving facial transplants also require lifelong treatment with immunosuppressant drugs.
15. From information gathered during the meeting with Professor Butler it is known that when similar transplants have been carried out in other countries, extra skin (from the donors arm or leg) has also been taken from the deceased facial tissue donor and transplanted onto another part of the recipients body (e.g. the arm or leg). This provides an area of donor tissue to biopsy if any rejection becomes clinically apparent in the recipient and allows the assessment of the levels of immunosuppressant drugs required. This practice prevents the need to biopsy the facial area. Bone marrow has also been taken from the donor in order that it can be transplanted to the recipient four to eleven days following the facial transplant. The aim of this practice is to reduce the risk of rejection.

How should the procedure be regulated?

16. Consideration needs to be given as to which provisions the storage and use of the extra skin and bone marrow will fall under. Having the facial tissue graft, and the bone marrow and extra skin regulated under different legislation could lead to a lack of clarity for the clinicians involved.

Consent

17. In common with organs, the activity of consenting for the donation of facial tissue for transplantation will be subject to the consent provisions of the HT Act. The consent provisions of the Act must be thoroughly applied in this novel procedure.

Recommendation

18. Composite tissue transplantation such as facial tissue grafts are considered as organs and will be within the scope of the ODD. Given the nature of the procedure, in particular the very short procurement time following ischaemic

death and the need for the graft to be transplanted immediately with no storage requirements, it is recommended that the activity of composite tissue transplantation should not be regulated under the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

19. Pending the ODD the procedure should be subject to the consent provisions of the HT Act.
20. It is however recommended that the bone marrow and extra skin procured during the retrieval operation for use in the same recipient as the facial tissue graft are regulated within the remit of the European Union Tissue and Cells Directives therefore under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. This would be similar to the current HTA policy on auxiliary vessels taken at the time an organ is procured for transplantation and stored for use in the same recipient as the organ or in another recipient.
21. Legal advice from HTA's Head of Legal is that there is no perceived regulatory or legal risk to the HTA not regulating composite tissues under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. More advice can be given when further information on the review of the definition of an organ is available*.

Outcome

22. Following the presentation of this policy to the Senior Management Team at HTA on 6 May 2010, the recommendations in this paper have been agreed as HTA policy. A proportionate and risk based decision is that composite tissues are considered organs, which means that they are regulated under the consent provisions of the HT Act and, in the future, the ODD.

Post script

23. Following the final publication of the Organ Donation Directive the designation of an organ has been defined as;

“organ” means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation.

For further information, please visit:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0053:EN:NOT>

24. This definition supports the decision made by the HTA earlier this year to consider composite tissue which maintains structure, vascularisation and a capacity to develop physiological functions as organs.

Authority paper

Date	25 January 2011	Paper reference	HTA (10/11)
Agenda item	14	Author	Vicky Marshment Jess Porter

Operation of the living organ donation system: October – December 2010

Purpose

1. This paper provides the Authority with an update on the living organ donation programme, specifically the number of reports submitted by Independent Assessors (IAs) to the HTA for assessment.
2. Last year the Authority received two updates on the living organ donation system, in March and September. The intention this year is for the Authority to receive a quarterly update. The next update will include trends during the last financial year.

Overview

3. Between 1 April 2010 and 7 January 2011, the Executive assessed 850 cases (all of which were approved) and an additional 74 cases were referred to a panel of Authority Members for decision (all but two of which were approved).
4. This update specifically covers the period from 1 October 2010 to 31 December 2010. A breakdown for each month is provided below and is outlined in table format at the end of the paper.

October

5. During October, the Executive assessed 103 cases and an additional three cases were referred to panel for decision. Of the cases referred to a panel, two were paired and one was for an adult-to-adult liver donation.

6. The average turnaround time for non-panel cases was 0.6 days against a monthly target of five working days. The average turnaround time for panel cases was 2.3 days against a monthly target of 10 working days.
7. 83% of cases received were fit for purpose at the point of submission. This was a new performance indicator for 2010-11 and is measured against a target of 75%.

November

8. During November, the Executive assessed 106 cases and an additional four cases were referred to panel for decision. Of the cases referred to panel, two were for non-directed altruistic donations and two were for adult-to-adult living liver donations.
9. The average turnaround time for non-panel cases was 0.8 days. The average turnaround time for panel cases was four days.
10. 90% of cases received were fit for purpose at the point of submission.

December

11. During December, the Executive assessed 63 cases and an additional 14 cases were referred to panel for decision. Of the cases referred to panel three were for non-directed altruistic donations, one was for an adult-to-adult liver donation, and 10 were for paired/pooled donations.
12. The average turnaround time for non-panel cases was 0.6 days. The average turnaround time for panel cases was 3.6 days.
13. 91% of cases received were fit for purpose at the point of submission.

Points to note

14. We are pleased to see that a significant proportion (88%) of IA reports received during this three month period met the standard required.
15. The reaccreditation process has begun and gives the opportunity to assess the standard of reporting for each IA.
16. All those IAs who have consistently performed below the level expected will be required to complete a refresher training package to familiarise themselves with the requirements of the Act and the information the HTA needs in order to make a decision on each case.

17. All the responses received from Authority Members regarding the new panel referral process were positive and this has made the whole process more efficient. We will therefore continue operating with this system.

	Percentage of reports fit for purpose at the point of submission	Total number of cases submitted	Total number of cases assessed by Executive	Total number of cases referred to a panel of Authority Members
October	83%	106	103	3
November	90%	110	106	4
December	91%	77	63	14

