

Annual Review 2010/11

Exercising efficiency

WITH THE INTERESTS of the public and those we regulate at the centre of our work; we aim to maintain confidence by ensuring that human tissue is used safely and ethically, and with proper consent. We regulate organisations that remove, store and use tissue for research, medical treatment, post-mortem examination, teaching and display in public. We also give approval for organ and bone marrow donations from living people.

We provide advice and guidance about two laws: the Human Tissue Act 2004 and the European Union Tissue and Cells Directives. The Directives were fully implemented into UK law on 5 July 2007, via the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). These laws ensure human tissue is used safely and ethically, with proper consent. Our aim is to set standards that are clear and reasonable, and in which both the public and professionals can have confidence.

In March 2011 the Human Tissue Authority was named as the Competent Authority for England and Wales for the EU Organ Donation Directive (EUODD) and we will take the lead on developing a regulatory framework and implementation into legislation by August 2012. The Directive will introduce a framework for quality and safety in order to maximise the benefits and minimise the risks of organ transplants across Europe. The Scottish and Irish Assemblies also asked us to be their Competent Authority for the EUODD and we have accepted.

The HTA's full Annual Report and Accounts are available on our website.



David



Magnus

Annual Review 2010/2011

Joyce



Janet



- 03 Chair and Chief Executive's introduction
- 04 The year at a glance
- 07 **Magnus Roseke**, Living Donor Coordinator, King's College London
- 09 **Janet Gibson**, Potential donor of tissues and body
- 11 **David Neal**, Deputy Director (Policy), National Research Ethics Service
- 13 **Joyce Robins**, Founder, Patient Concern
- 14 The HTA in numbers
- 16 The year ahead

A decorative graphic consisting of four overlapping circles. One circle is dark purple and contains the text 'Welcome to the HTA's sixth Annual Review'. The other three circles are light blue. The circles overlap in a way that creates a sense of depth and movement.

Welcome
to the HTA's
sixth Annual
Review



Chair and Chief Executive's introduction

WELCOME TO THE HTA's sixth Annual Review. The last year has been busier than ever and there have been major milestones and achievements along the way.

In July 2010, the Government published the arm's-length bodies (ALB) review. It recognised the essential nature of the HTA's functions, and the importance of our work continuing, but proposed these functions be transferred to other bodies.

We believe the best way to ensure public and professional confidence in the safe and ethical use of tissues and organs, with proper consent, is to keep all our functions together. The signs from Government are positive as this is now their preferred solution, though there are still some issues to settle in research. We will continue to support decision-making to help ensure the best possible outcome. We expect any transfer will happen over the lifetime of this parliament, most likely in 2014. In the meantime our work remains as important as ever. We will continue our work to a high standard and in a clear and reasonable way, in which both the public and professionals can have confidence. It is business as usual.

In September, we received the results of an independent survey and were delighted to see the importance people place on the regulation of human tissue. Over the last three years public confidence in human tissue regulation increased from 52 to 57%; and 86% of professional stakeholders have confidence in the HTA. The more confidence there is that tissue will be used

safely and ethically the more likely it is that people will donate for the good of medicine and science. We also continue to receive extremely positive feedback from our inspections.

But we are not complacent, and your views are of great value in making sure we are even more efficient, effective and responsive to the public and those we regulate. Over the last year, we have established new links with public groups and built on our relationships with the post mortem sector. For example, by setting up the Histopathology Working Group and engaging with Pathologists, Coroners, and key partners, we can better address issues affecting public and professional confidence.

As we refine our inspection methods, licensed sectors can look forward to a more streamlined approach which aims to make regulation as pain free as possible whilst ensuring public confidence is maintained. They will also see increased efficiency and a significant reduction in licence fees. As ever though, we will take action when necessary to ensure the safe and ethical use of human tissue and organs.

Last year we saw a doubling in the number of amazing people who have been willing to donate their kidney to a complete stranger and more and more living people are coming forward to donate organs. This welcome trend is inevitably accompanied by increasingly complex issues, both practical and ethical.

We continue to be a dynamic and forward-looking regulator, and have taken on new responsibilities this year. As testament to our expertise, we were appointed in March by the Government and devolved administrations to implement the European Union Organ Donation Directive. The Directive will introduce a framework for quality and safety in order to maximise the benefits and minimise the risks of organ transplants across Europe.

As well as implementing the Directive, our focus over the coming year will shift to engaging more directly with the public, seeking their views and ensuring they influence our work, so we have a balance of public and professional views.

We hope this Review and the case studies included give you an overview of our efficiency, effectiveness and the value for money we provide to ensure public and professional confidence.

Finally, we thank HTA staff and Authority Members, old and new, for all their hard work and professionalism over the last year.



Baroness Diana Warwick
Chair



Craig Muir
Chief Executive

The year at a glance



100% of respondents rate the **HTA inspection process** as either **'good'** or **'excellent'**

APRIL – JUNE

- We welcome **four new Authority Members**: Professor Susan Dilly, Rosie Glazebrook, Suzanne McCarthy and Professor Gurch Randhawa.
- More people come forward to be living donors; this includes a **50% increase** in the number of prospective altruistic kidney donors.
- We ask the post mortem sector to **conduct an audit of tissue samples** stored on their premises.
- We introduce a **Serious Untoward Incident (SUI)** reporting system for the post mortem sector.
- We respond to a **surge in public enquiries** about body donation following the BBC's coverage on The One Show.
- We present at the **first tripartite scientific meeting** of the Institute of Anatomical Sciences, Anatomical Society of Great Britain and Ireland and the British Association of Clinical Anatomists.
- We take the lead for a work package for the European Union **Substances of Human Origin Vigilance and Surveillance (SoHO V&S)** project.

JULY – SEPTEMBER

- We welcome our **new Chief Executive**, Craig Muir.
- The Department of Health announces the **arm's-length bodies (ALB)** review which proposes to transfer our functions by the end of the current Parliament.
- We publish a press release about an HTA inspection of Cardiff's University of Hospital Wales Llandough (University Hospital Llandough) which demonstrates that its **post mortem facilities are an example of best practice**.
- Our Chair **Baroness Diana Warwick** presents at the joint Medical Research Council and onCore UK conference, *Sharing Human Tissue: New opportunities, new horizons*.
- We **submit further evidence** to the Academy of Medical Science's review of the regulation and governance of medical research.
- After consultation with stakeholders across the five sectors we license, we announce significant reductions in 2011/12 licence fees for all sectors, and for most establishments. **We make efficiencies that will reduce our fee income by 14%**.

OCTOBER – DECEMBER

- We publish findings from an Ipsos MORI poll showing a five percentage point **increase in the proportion of British adults who have confidence in human tissue regulation** – from 52% to 57%. Nearly nine in ten (86%) professional stakeholders have confidence in us as a regulator, with two in five saying their **confidence has increased in the last three years**.
- The Government announces that it is intending to use a Public Bodies Bill to put in place the **legal framework to reform public bodies**. Debate on the Bill starts in the House of Lords.
- Sir Gordon Duff's **review of the Organ Donor Register** is published, it recommends that the Register be modernised and further developed to reflect the wishes of those people registered.
- We hold our **tissue and cells for treatment (human application) sector conference** in Nottingham.
- We **move to a new office** to co-locate with the Medicines and Healthcare products Regulatory Agency, the Health Protection Agency and NHS Litigation Authority.

- **100% of respondents rate the HTA inspection process as either 'good' or 'excellent'** (the majority selecting the 'excellent' category) in feedback collated at site-visit inspections throughout 2010/11.
- We **publish a new webpage** dedicated to helping members of the public find their nearest medical school and learn more about body donation.
- We **publish a consolidated guide** to quality and safety assurance for human tissue and cells for patient treatment.
- We **publish guidance** for the cord blood stakeholders in the tissue and cells for treatment sector.
- Our CEO Craig Muir meets the Coroners Advisory Group to **listen to members' concerns** about Human Tissue Act requirements and explore how we can work with, and support, Coroners.
- We meet with the Clinical Pathology Accreditation to **discuss potential for collaborative working**.
- We **pay licence fee rebates** to establishments of £1.142m.

JANUARY – MARCH

- We are **confirmed as the Competent Authority** for England and Wales for the EU Organ Donation Directive (EUODD) across the UK.
- We start to **publish inspection reports online**.
- We hold the first meeting of the **HTA histopathology working group** (formerly the post mortem sector working group).
- We start working with the Department of Health and NHS Blood and Transplant on **implementation of the EUODD**.
- We complete the reaccreditation of **132 Independent Assessors**.





TRANSPLANT

The HTA's system is very efficient ... It is a smooth process; good for the regulating authority and good for patients. Magnus Roseke

Magnus Roseke, Living Donor Coordinator, King's College London

"I HAVE BEEN a Living Donor Coordinator for just over seven years now and I am mainly responsible for coordinating the medical work-up of potential living kidney donors. My role is very much focused on making sure that potential donors are properly evaluated from a medical and psychological point of view in order to ensure their suitability for live donation.

"At first contact, I usually spend 1–2 hours with the patients explaining all aspects of the donation process, including the role of the HTA. I have oversight of the tests and processes necessary to ensure that a potential living donor is suitable.

"If, after the initial consultation, the person is happy to continue the process towards donation, we tend to start the process with a range of blood tests. If initial screening shows the donor to be suitable, we continue the work-up with more invasive investigations such as nuclear medicine tests and CT scans. We also like to give a donor some time to think things through to make sure they have made a decision that is right for them.

"The HTA's involvement is to assess each prospective organ donation case on the basis of the evidence of

test results and to ensure the donation is appropriate in accordance with the Human Tissue Act. A donor and recipient need to provide evidence of their relationship and there must not be any form of coercion involved in the process. We work closely with the HTA and with their Independent Assessors (IAs), who carry out the interviews with potential donors and recipients to work out if there are missing pieces of information or if we need to find alternative sources of information.

"The current HTA system is very efficient. As a general rule, we have approvals come through the following day after an IA interview. It is quick and flexible and the system is done online, with no lengthy paperwork. It is a smooth process which is good for us, good for the regulating authority and good for patients.

"The HTA is on the whole easy to deal with, and there is always someone at the other end of the phone. The HTA is very accommodating as well – recently, a few members of the HTA staff came to King's College Hospital to conduct training for a whole day in order for us to get some more IAs trained and accredited. I think this shows flexibility and that the HTA wants this process to work."

THIS YEAR WE approved 1,207 living organ donations and 67 bone marrow donations. Successes in the transplant sector have been maintained with an increase in the number of people who come forward to be living donors, including a 50% increase in the number of prospective altruistic kidney donors.

We continue to provide tailored training for our Independent Assessors (IAs) who interview living organ donors and recipients, and our Accredited Assessors (AAs) who interview bone marrow donors and recipients. As well as providing the most up-to-date statistics via our e-newsletter, we provide advice and guidance to transplant units via special bulletins and leaflets. In 2010/11 our updated living donation leaflet was downloaded 668 times.

To advise and inform as many people as possible, we continue to make our leaflets available in multiple languages on our website. The Arabic version of our bone marrow donation leaflet was downloaded 267 times in 2010/11.

We have trained more HTA staff to use our online submission system for transplant approvals. This means that we can be more efficient in approving IA and AA reports.

This year we approved **1,207** living organ donations





**POTENTIAL
DONOR**

We are a nation of givers. People are prepared to help others; people are happy to be helpful.

Janet Gibson

Janet Gibson, potential donor of organs and body

"I HAVE ALWAYS considered donating my body and organs and I carry an organ donor card. I'm quite happy to donate – but there needs to be regulation. People are not going to donate if they don't have the guarantee that there is an experienced body that monitors, regulates and licenses the process.

"In order to donate we need to have confidence in the system. We are a nation of givers. People are prepared to help others; people are happy to be helpful.

"It's important that the public is given the right information and independent opinion – and that we are sure that any donation will be professionally carried out. We want to know that a suitable system and organisation is in place to handle this.

"What I am looking for is expert, professional and medical reassurance – the existence of an efficient regulator such as the HTA provides this for me."

Over the last year, we received

4,107 enquiries ...
1,992
of which were about
body donation

OUR EVALUATION OF public opinion shows that people are more confident to donate tissue knowing that there is a regulator: 48% would be more confident to donate tissue for medical research; 52% would be more confident to donate organs for transplant, and 43% would have greater confidence donating their bodies for medical education and training. Our work helps support healthcare outcomes.

We license and inspect establishments which use donated bodies, such as medical schools. We also provide information packs about body donation for the public.

Our expert advice and guidance is sought after. Over the last year, we received 4,107 enquiries including 2,688 from members of the public; 1,992 of which were about body donation – consistently our top enquiry.



RESEARCH

As a result of this streamlined and popular scheme, ethics committees have approved more than 200 tissue banks.

David Neal

David Neal, Deputy Director (Policy), National Research Ethics Service

"I AM THE Deputy Director (Policy) of the National Research Ethics Service (NRES). NRES comprises 80 Research Ethics Committees (RECs) in England and their management support. We also work closely with colleagues in Wales, Scotland and Northern Ireland to provide a coordinated system of ethical review across the UK.

"Right from when the HTA was established, it was clear that NRES and the HTA shared a common aim to balance the protection of the rights of research participants and tissue donors with encouraging research using donated tissues for the benefit of science and society. We shared key values in seeking a proportionate, facilitative and transparent approach to research regulation. The licensing and ethical review functions needed to work together without unnecessary duplication. Consistent interpretation of the Human Tissue Act (HT Act) was essential to avoid uncertainties among researchers, sponsors and RECs themselves. For NRES it was also important to ensure that ethical review of research involving tissue operated in a legal framework supported by the HTA.

"It was therefore crucial to establish close links from the outset. A great deal of progress has been made. We have a formal Memorandum of Understanding, and we meet and correspond regularly, for example on complex enquiries. We work with the HTA to agree consistent guidance and signpost researchers to our respective websites. As a result of our joint efforts, there is greater clarity, and we now receive fewer enquiries; on what types of tissue are regulated under the HT Act or when ethical approval must be obtained. NRES and the HTA have also collaborated effectively on a joint training programme for RECs and the research community to increase understanding, particularly around consent issues.

"We streamlined the approval process whereby research ethics committees can give generic ethical approval for a research tissue bank's arrangements for the collection, storage and release of tissue – providing the bank's tissue is stored on HTA-licensed premises. This has resulted in more than 200 tissue banks being approved.

"We believe this coordinated approach is reassuring to researchers and has been of benefit in encouraging research within the framework of the HT Act."

THE HTA LICENSES 255 establishments that store human tissue for research with 16 new establishments applying in 2010/11. In addition we estimate that at least 200 establishments licensed for post mortem and patient treatment also conduct research under their licence. We believe that good regulation supports good science, which in turn improves healthcare. We know that research translates directly to revolutionary patient treatment. For example, one of our Designated Individuals in the patient treatment sector was involved in the pioneering procedure on the first child in the world to undergo an operation to rebuild his windpipe using his own stem cells.

Though the Academy of Medical Sciences' review of the regulation and governance of medical research recognised the HTA as providing improved clarity for researchers, it did propose transferring our research functions to a new health research regulator. We expressed our belief that this proposal would not achieve simplification, reduce burdens or achieve savings.

In 2010/11 we announced we will reduce license fees. In the research sector they will decrease by 30%; and in the post mortem sector by 11%.

The HTA continues to work with NRES and to support the research community more widely.

The HTA licenses **255** establishments that store human tissue for research



THE PUBLIC'S
PERSPECTIVE

I see the HTA as a
bastion; protecting
the rights of our
bodies ... The
reason the HTA
was set up has not
gone away – we
ignore this at our
peril. Joyce Robins

Joyce Robins, Founder, Patient Concern

"I AM A founder of Patient Concern, which I helped form 11 years ago. Patient Concern is a non-profit organisation committed to promoting choice and empowerment for all health service users. It operates as a network of patients, carers, lawyers, journalists, ethicists and human rights activists, and is active in all areas of the health service, campaigning on patient issues.

"Consent is one of our main issues, and we have made a lot of strides on this. The level of caution exercised,

with regards to consent is not excessive, and most patients would agree. This is the relevance of the HTA. I see the HTA as a bastion; protecting the rights of our bodies. The Human Tissue Act is the golden thread which runs through everything, protecting our tissues and organs and the HTA makes sure this happens. We welcome this; it is an extremely valuable thing as providing people with the right information is very important to them. The reason the HTA was set up has not gone away – we ignore this at our peril."

86%

of professional stakeholders have confidence in the HTA as a regulator,

with **2** in **5** saying their confidence has increased in the past **3** years

THE GOVERNMENT RECOGNISES that our functions are essential in safeguarding consent and ensuring the safe and ethical use of human tissue and organs. The HTA was set up in response to the organ retention scandals which caused public outrage.

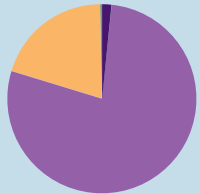
Since its inception the HTA has turned this public confidence crisis around. Confidence in human tissue regulation has increased following our initial poll in 2007. Our second survey demonstrated a five percentage point increase in the proportion of British adults who have confidence in human tissue regulation – from 52% to 57%. 86% of professional stakeholders have confidence in the HTA as a regulator, with two in five saying their confidence has increased in the past three years.

We believe that the proposals in the arm's-length bodies review to split up and transfer our functions to different organisations risk undermining the progress that has been made. Our views are shared. For example, medico-legal academics and consultant surgeons have used the media to express their concern about the proposed division of the HTA.

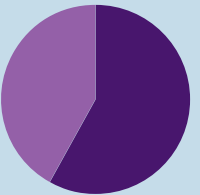
More recently the Government has said, that in light of the strong arguments put to it, its preferred option is for all our functions to be kept together and transferred to the Care Quality Commission, though further thought is being given to our research functions.

The HTA in numbers

SUMMARY OF THE HTA'S OPERATIONS IN 2010/11



Income Source	Amount (£000s)
Income from devolved administrations	100
Licence fee	4,141
Government Grant-in-Aid	1,059
Other income	5
Total income	5,305



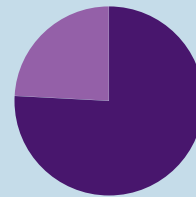
Expenditure Category	Amount (£000s)
Staff costs	3,104
General administrative costs	2,233
Total expenditure	5,337

NOTE: This is a summary only. The HTA's Annual report and Accounts are available on our website.

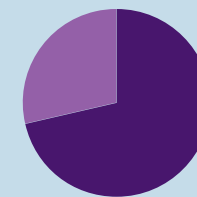
NUMBER OF ESTABLISHMENTS WE LICENSE

Number of licensed organisations by sector in 2010/11

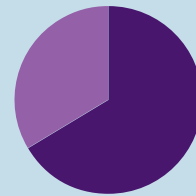
● Main sites ● Satellite sites



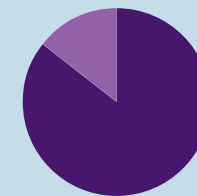
Post mortem ● 216 (11)
● 68



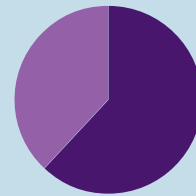
Anatomy ● 35 (1)
● 14



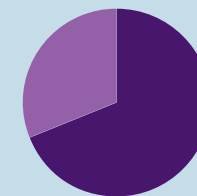
Tissue and cells for treatment (human application) ● 175 (25)
● 88



Public display ● 18 (3)
● 3



Research ● 158 (16)
● 97



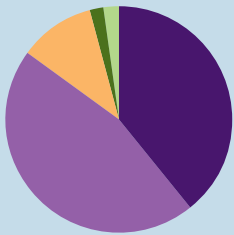
Cumulative total ● 602
● 270

NOTE: The numbers in brackets represent the total amount of new licences we have issued per sector in 2010/11. Satellite sites are premises operating under the same governance and supervisory arrangements as the main site.



412,000 website hits

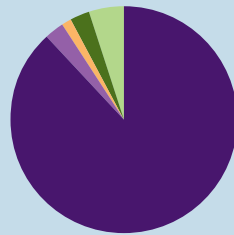
NUMBER OF INSPECTIONS



Post mortem	76
Tissue and cells for treatment (human application)	89
Research	21
Anatomy	4
Public display	4
Total	194

During the 2010/11 business year we completed 194 site-visit inspections (89 tissue and cells for patient treatment, 21 research, four anatomy, 76 post mortem and four public display).

NUMBER OF ORGAN AND BONE MARROW DONATIONS FROM THE LIVING WE APPROVED



Number of living organ donations	1,207
<i>(6% increase on previous year)</i>	
Number of altruistic donations	40
Number of paired organ donations	18
Number of pooled (three-way exchange) organ donations	38
Number of bone marrow donations	67

COMMUNICATION IN 2010/11

Website hits
412,000

Individual visitors to website
172,000


E-newsletter subscribers
7,000

Number of enquiries
4,110

E-newsletter subscribers
7,000



The year ahead 2011/12



Our overall strategic goal is to maintain **confidence** in the **removal**, **storage** and **use** of **human tissue**

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

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

We will reach our goal by fulfilling four strategic aims:

STRATEGIC AIM ONE

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

High level objectives 2011/12:

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

STRATEGIC AIM TWO

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

High level objectives 2011/12:

- To maintain confidence in the regulation of the removal, storage and use of human tissue amongst professionals and the public.
- To manage the reputation of the HTA effectively.
- To engage stakeholders to inform regulatory and organ donation policy and processes.
- To work with Government and other relevant organisations to ensure, that in any changes resulting from the arm's-length bodies review, human tissue continues to be removed, stored and used safely and ethically.

STRATEGIC AIM THREE

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

High level objectives 2011/12:

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

STRATEGIC AIM FOUR

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

High level objectives 2011/12:

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



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