Annual report and accounts : 2009/10 / Human Tissue Authority.

HTA
Human Tissue Authority

MAKING A DIFFERENCE

HUMAN TISSUE AUTHORITY
ANNUAL REVIEW 2009/10

The **Human Tissue Authority** (HTA) is an independent regulator responsible for licensing organisations that store and use human tissue for purposes such as research, patient treatment, post-mortem examination, teaching and public exhibitions. We also give approval for organ and bone marrow donations from living people and oversee the consent requests for deceased organ donation.

We provide advice and guidance about two laws: the Human Tissue Act and the European Union Tissue and Cells Directive. These laws ensure that bodies and human tissue are used safely and ethically, and that people's wishes are respected. They also protect the interests and ensure compliance with the wishes of living donors of organs and bone marrow. Our aim is to set standards that are clear and reasonable, and in which the public and professionals can have confidence.

This Annual Review covers the period 1 April 2009 to 31 March 2010. The HTA's full Annual Report and Accounts are available at: **www.hta.gov.uk/publications/annualreviewsandreports.cfm**

The HTA's 5th Annual Review

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Annual Review 2009/10

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We license more than **850** premises

Chair and Chief Executive's INTRODUCTION

Welcome to the HTA's fifth Annual Review. Since we began regulating in 2006, we have been well on the way to achieving our aim of becoming a high-performing and forward-looking regulator. We now license more than 850 premises and have approved 3,000 organ donations from living people.

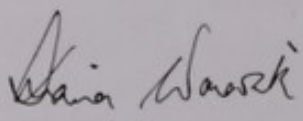
We have faced new challenges over the last year. These include the impact of the economic downturn, increased awareness of patient safety issues and rapidly advancing medicine and science. We have continued to put emphasis on securing compliance through the provision of advice and guidance rather than enforcement. But we have not shirked taking proportionate regulatory action when poor compliance with HTA standards has made it necessary to do so.

The Hampton Implementation Review, published by the Better Regulation Executive in July 2009, commended us for our minimal inspection and data-collection burdens and the quality and availability of our advice and guidance. We have also received positive feedback from professionals and other regulatory bodies, including those in the European Union. You can read comments from some of the people we regulate in case studies we highlight in the following pages.

We hope this Annual Review paints a picture of our efficiency and effectiveness, and how we make a difference as a regulator. We also hope it shows that, by raising standards, we have continued to maintain the confidence of the public and professionals.

As we move into the next year, we will continue to work closely with the people we regulate to ensure our decisions are based on the best available evidence. While avoiding unnecessary burdens on licence fee payers and the public purse, we will work to assure the public that tissue is taken or used only with their consent and is safe when used in patient treatments. In doing so, the HTA will continue to make an important contribution to healthcare advances in science and medicine.

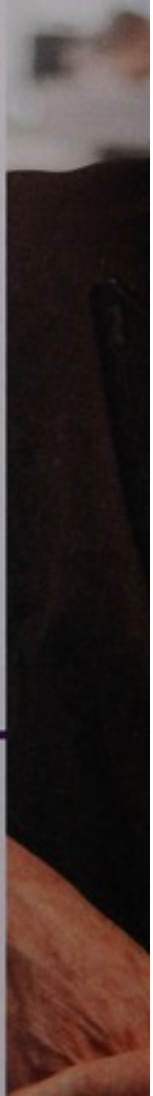
Shirley Harrison stepped down on 31 December from her role as Chair of the HTA after her three-year term and a new Chief Executive will be appointed in the summer. We will build on the firm foundation provided by the outgoing Chair and Chief Executive to develop new ideas and approaches. This will enable us to further develop our good reputation and make the HTA even more efficient, effective and responsive to the fast-changing regulatory and scientific environment.



Baroness Warwick, Chair

Adrian McNeil, Chief Executive

Our achievements and activities in 2009/10



WE WILL CONTINUE TO **WORK CLOSELY** WITH THE PEOPLE WE REGULATE TO ENSURE OUR DECISIONS ARE BASED ON THE **BEST AVAILABLE EVIDENCE**

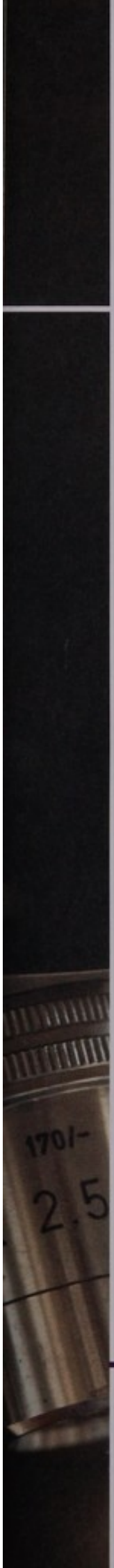
How we made A DIFFERENCE in 2009/10

APRIL – JUNE

- We launch a new website, which features a more user-friendly structure and design, an improved search facility, links to the most popular pages and news feeds
- We announce a 50% increase in the number of people approved to donate a kidney to someone they do not know (15 people in 2008/09 compared with 10 in 2007/08)
- We contribute to a collaborative project with the Department of Health and other regulators to launch the UK Stem Cell Tool Kit – a resource for those who wish to develop a programme of stem cell research and manufacture, ultimately leading to clinical application
- We begin licensing establishments that carry out activities involving acellular tissue and cell products used for patient treatment

JULY – SEPTEMBER

- The Better Regulation Executive publishes its report of the Hampton Implementation Review of the HTA, which praises the HTA for being risk-based, proportionate and transparent
- We hold our review of the year event, which includes an interactive debate on cord blood and an audience discussion on HTA strategy
- Seven revised codes of practice and an entirely new code for research come into force following public consultation
- We issue a joint position statement with the National Research Ethics Service that sets out licensing, ethical approval and consent requirements for diagnostic archives that function as research tissue banks
- We move to a continuous licensing system for all sectors
- We publish revised guidance for transplant teams and Independent Assessors
- We hold a public Authority meeting in London



50% increase in the number of people approved to donate a kidney to someone they do not know

OCTOBER – DECEMBER

- We issue six summary compliance reports
- We hold a conference for the post mortem sector
- We issue a flowchart for coroners' post-mortem examinations to support communication between pathologists, coroners and families
- We issue a regulatory alert to Designated Individuals in the post mortem sector on compliance with standards and the retention of tissues and organs
- We hold a conference for Independent Assessors in London
- We publish a revised model consent form with suggested formats for obtaining consent for the post-mortem examination of adults
- We liaise with other government departments to develop the Coroners and Justice Bill which received Royal Assent in November 2009
- Research evaluation project on the impact of legislation and HTA regulation reveals perceptions of the research community
- We approve the 3,000th living organ donation
- We publish new guidance about consent and the use of DNA
- We move to a continuous licensing system for the human application sector
- We launch a new publication scheme to increase the information we publish, including information on expenses

JANUARY – MARCH

- We publish updated advice and guidance on umbilical cord blood collection for professionals and the public
- We attend meetings of the All-Party Parliamentary Group on Umbilical Cord Blood and Adult Stem Cells
- We introduce more efficient HTA Information Technology systems
- We announce the UK's first pooled transplant
- We work with the Department of Health and NHS Blood and Transplant to communicate directed deceased allocation guidance
- We work with the Medicines and Healthcare products Regulatory Agency to carry out a pilot joint inspection
- We meet to discuss common areas of interest with the Coroners Advisory Group
- We launch a licence fees consultation, following workshops in 2009
- We hold a public Authority meeting in York

6 summary compliance reports published

VASSILIOS PAPALOIS

CONSULTANT TRANSPLANT SURGEON
HAMMERSMITH HOSPITAL, IMPERIAL COLLEGE HEALTHCARE NHS TRUST

1,140
organ donations approved

"I WORK in the West London Renal and Transplant Centre at the Hammersmith Hospital, which is the biggest unit of its kind in Europe. Our team performs more than 200 organ transplants every year, and almost half of them are living donor kidney transplants. Our programme increases every year and we offer our patients live donor kidney transplantation as their first and best option, ideally before they even go on dialysis.

"We now accept more challenging cases of donors and recipients for living donor kidney transplantation. Our team has also developed the biggest programme in the UK for facilitating antibody removal to enable transplants between certain donors and recipients who are blood group incompatible, so the transplant is less likely to be rejected.

"The support of the HTA, in its coordination of transplant approvals, has been vital in enabling these new technologies to be applied, and has helped us get this project off the ground, increasing the number of successful transplants.

"Before patients become involved in transplant operations, Independent Assessors (IAs) make sure they understand the potential risks. The HTA coordinates this process in an objective, supportive and efficient way. Communication and confidence are paramount.

"The HTA was instrumental in helping to facilitate paired transplants. This involves exchange of kidneys between two donor and recipient pairs for whom the transplant was not originally possible due to blood group or tissue incompatibility. Our centre was recently involved in the first three-way exchange live donor kidney transplant for which the HTA played a crucial and always helpful role.

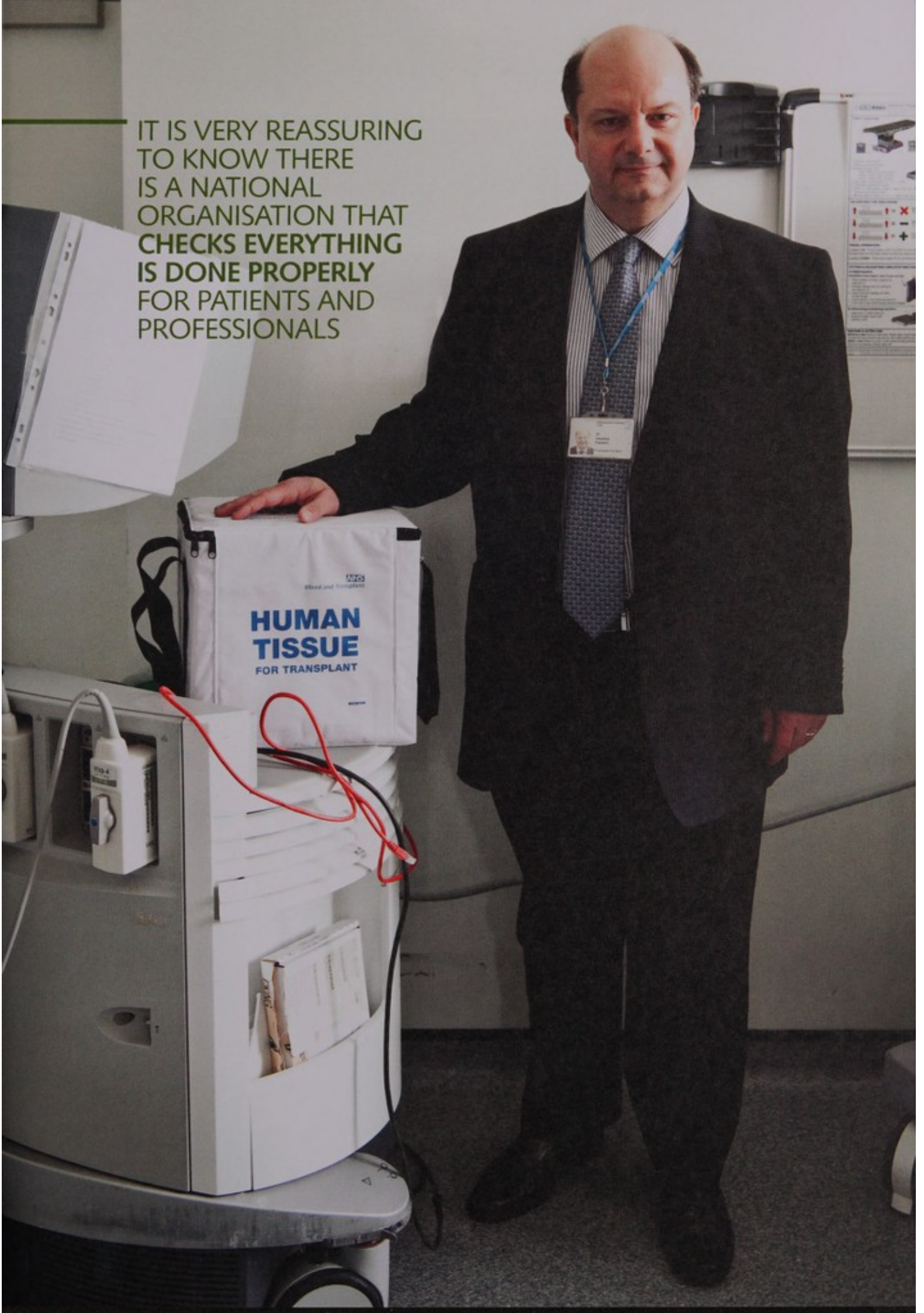
"Although we do our homework well, it is still very reassuring to know there is a national organisation that checks everything is done properly for patients and professionals. The HTA protects the interests of those involved in transplants, and the reputation of transplantation in the UK."

THIS YEAR, the HTA approved 1,140 organ donations and 78 bone marrow donations and there were several landmarks in living organ donor transplants. There included a 50 per cent increase in the number of altruistic kidney donations and the HTA's 3,000th living organ donation approval. We also approved the first three-way organ transplant in the UK.

We are continuously improving our advice and guidance for professionals and the public. During the year, we provided training for transplant professionals at the IA conference, and published revised guidance for transplant teams and IAs, which reflects our new code of practice. We also launched a new online submissions system for transplant approvals.

We contributed to the Department of Health and NHS Blood and Transplant (NHSBT) review of directed deceased allocation, which strikes a balance between allowing, in very rare cases, organ donation to be allocated to a friend or relative, and protecting the key principle that priority is given to those in greatest need.

In a broader context, following feedback from our audiences, we launched a new, improved HTA website in June, which includes a new section on donating human tissue. During the year, we also sent out six issues of our e-newsletter, which now has 6,500 subscribers.


IT IS VERY REASSURING TO KNOW THERE IS A NATIONAL ORGANISATION THAT **CHECKS EVERYTHING IS DONE PROPERLY** FOR PATIENTS AND PROFESSIONALS
HUMAN TISSUE
FOR TRANSPLANT

I SEE THE HTA AS A POINT OF REFERENCE THAT **ENABLES ME TO SPEAK WITH AUTHORITY** WHEN GIVING ADVICE ON CORD BLOOD COLLECTION

JANET FYLE

MIDWIFE AND PROFESSIONAL POLICY ADVISER
ROYAL COLLEGE OF MIDWIVES

"I AM A REGISTERED MIDWIFE and the Professional Policy Adviser at the Royal College of Midwives (RCM). My role involves providing midwifery advice to the RCM and our midwife members, and looking at how local and national policies affect women, their families and midwives.

"One of the issues that the RCM has been engaged with recently is advising our members on the safety, quality and legal implications of collecting cord blood. The HTA helps me tailor the advice about its policies and regulations. I see the HTA as a point of reference that enables me to speak with authority when giving advice on cord blood collection. For example, I can inform midwives there is a body that regulates cord blood collection and I can always say: "This is what the HTA says." And that in itself carries weight.

"In the last year, the HTA's communication with midwives has been very good. The website is extremely useful and the information is in a digestible format. We know that midwives are very busy people and we can say to them: "Just click here to find the most up-to-date information on policies or regulations in this area..." It saves people having to explain these issues secondhand.

"I am also impressed that the HTA is willing to engage in open discussions with people it regulates and make improvements as a result. At one of the HTA's annual meetings, I had the opportunity to speak to staff and Authority Members about issues I thought were important, not only to midwives, but to members of the public. They did take notice of my comments. In effect...they listened."

120 people participated in a lively debate on cord blood banking

IN MARCH, the HTA wrote to more than 150 organisations highlighting concerns that umbilical cord blood collection may have been taking place unlawfully, which could risk the safety of the mother and baby, and compromise the quality of the sample collected. We also published guidance on our website for professionals and the public, and attended meetings of the All-Party Parliamentary Group on Umbilical Cord Blood and Adult Stem Cells.

At our review of the year event in July, 120 people participated in a lively debate on cord blood banking. The audience was made up of people we regulate from the public and private sectors, as well as those affected by our regulation. The discussion allowed the audience to voice their ideas and views on the future of cord blood banking and gave the HTA valuable information for our cord blood communications and regulatory strategies.

During the year, we improved our transparency generally, increasing the information that we publish to include information on expenses. We also held two public Authority meetings, in London and York, and launched our licence fees consultation in March, following workshops in 2009.

The HTA's communication with midwives has been very good

DAVID HADDOW

OPERATIONS DIRECTOR
ALTRIKA LTD

"I AM A DESIGNATED INDIVIDUAL at a company called Altrika, which is based in Sheffield. We offer a cell culturing service that delivers skin cells to patients in the UK with severe burns and chronic wounds, for whom few treatments are available.

"The company's activities are diverse. We source cells from hospitals, and subsequently process, distribute and store them. Part of the process – the collection of cells and obtaining consent from donors – falls under the remit of the HTA's regulation, as does cell storage. Inspection of the processing and distribution activity is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA), which regulates the quality and safety of medicines.

PREPARING FOR INSPECTIONS IS NOT TRIVIAL SO **A SINGLE INSPECTION IS A TIME-SAVER**

"A joint inspection with both regulatory agencies, with an aligned inspection process, is therefore very sensible. Preparing for inspections is not trivial so a single inspection is a time-saver. This reduces time taken for assembling documents and bringing together staff, as well as streamlining the post-inspection burden and allowing more time to concentrate on our core activity, which is preparing treatments for patients.

"We work in a fast-moving sector and it is important that new clinical approaches are regulated in an appropriate way, and that the public are aware of this. Investors in new technologies also need to be confident that the right regulatory framework is in place in order to plan effective clinical development programmes."


WE WORK IN A FAST-MOVING SECTOR AND IT IS IMPORTANT THAT **NEW CLINICAL APPROACHES ARE REGULATED** IN AN APPROPRIATE WAY

IAN REES

SENIOR INSPECTOR
MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

"MAINTAINING OUR INVOLVEMENT with the HTA's activities helps us to see different ways of working and ensure that there are no regulatory gaps between the work of the agencies. The reduced administrative burden and provision of advice and guidance fits in with principles from the Hampton Implementation Review, carried out by the Better Regulation Executive. We are looking for other opportunities to continue with pilot joint inspections."

GREG NEAL

REGULATION MANAGER
HUMAN TISSUE AUTHORITY

"THE HTA REGULATES tissues and cells used in patient treatment. When these tissues and cells, or products derived from them, become classified as medicinal products, they are regulated by the MHRA.

"For some time, the MHRA and the HTA have discussed ways of improving the efficiency of regulation of processes that may fall under the remits of both the MHRA and the HTA, to help reduce the time establishments spend preparing for inspections.

"The HTA undertook a pilot joint inspection with the MHRA. This joint approach meant the establishment had to prepare for only one inspection. We were able to work with the MHRA to share information on inspection approaches and define where our regulatory remits adjoin. We also found it beneficial to understand Altrika's production process from beginning to end, so that we could put the HTA's regulatory remit in context."

AT THE HTA, we constantly aim to improve the way we regulate and to reduce the burden on licensed establishments. Following feedback from the licensed sectors, we moved from a fixed-term licensing system to a more efficient continuous licensing system, which reduces the administrative burden on establishments and the HTA.

The HTA works closely with other regulators in the UK and in Europe. Collaborating with the Department of Health and other organisations, we contributed to the launch of the UK Stem Cell Tool Kit – a single resource for those who wish to develop a programme of stem cell research and manufacture, ultimately leading to clinical application.

During the year, we held meetings of our tissues and cells working group, some of which were attended by MHRA inspectors, to ensure effective working and consistency between regulatory bodies.

In our role as a Competent Authority under the EU Tissues and Cells Directives, we received and investigated adverse event and reaction reports, and collected annual activity data from establishments in the human application sector. These data are submitted to the European Commission so that it can monitor the safety, quality and use of tissues and cells within the EU.

WE ARE **LOOKING FOR OTHER OPPORTUNITIES** TO CONTINUE WITH PILOT JOINT INSPECTIONS


This year, we published 7 revised codes of practice
and a new code for research

BRIDGET WILKINS

HISTOPATHOLOGIST
GUY'S & ST THOMAS' NHS FOUNDATION TRUST

"GUY'S AND ST THOMAS' Hospital Trust in London was one of the first establishments to license its diagnostic archive of histopathology specimens as a research resource, as part of our HTA licence covering post mortem activities.

HTA REGULATION IS IMPORTANT BECAUSE WE NEED AN **EFFICIENT PROCESS** TO ENSURE THAT **APPROPRIATE CONSENT** IS SOUGHT FROM HUMAN TISSUE DONORS

"The HTA helped considerably to clarify and support this process. Staff at the HTA have been responsive and flexible, and our recent inspection was useful in developing our Trust's consent policies, which have now been fully upgraded to reflect HTA requirements for post-mortem examinations. Our interactions with the HTA inspection team were very positive and we received prompt feedback.

"HTA regulation is important because we need an efficient process to ensure that appropriate consent is sought from human tissue donors. We now have standard post mortem consent forms and fewer delays with this paperwork, which raises everybody's confidence that appropriate procedures are being followed in a compliant manner.

"Professional confidence in the regulations governing human tissue storage for research is also important. For example, support from the HTA was very helpful for us in approaching our Trust management with proposals to licence our diagnostic archive for research and upgrade consent processes in line with this."

THIS YEAR, the HTA published seven revised codes of practice and a new code for research. These codes support professionals by giving advice and guidance based on experience, and reflect comments received during the consultation process.

We also carried out an evaluation of perceptions of how human tissue legislation and the HTA's regulation have affected researchers working with human tissue. Following the evaluation, we met representatives from the research sector, to agree how we can work together to streamline our regulatory approaches and ensure researchers understand the context and requirements of the HTA's regulation.

Working with the National Research Ethics Service, we developed a joint position statement which sets out licensing, ethical approval and consent requirements for diagnostic archives that wish to function as research tissue banks. These banks give researchers wider access to high-quality human tissue.

In July, the HTA was rated highly on provision of advice and guidance and minimisation of inspection and data collection burdens by the Better Regulation Executive in its Hampton Implementation Review. We further improved our efficiency, effectiveness and value for money by refining our Information Technology systems.

IN CONSULTATION WITH CORONERS, PATHOLOGISTS, MORTUARY MANAGERS AND THE MINISTRY OF JUSTICE, THE HTA **DEVELOPED A MODEL COMMUNICATION FLOWCHART**

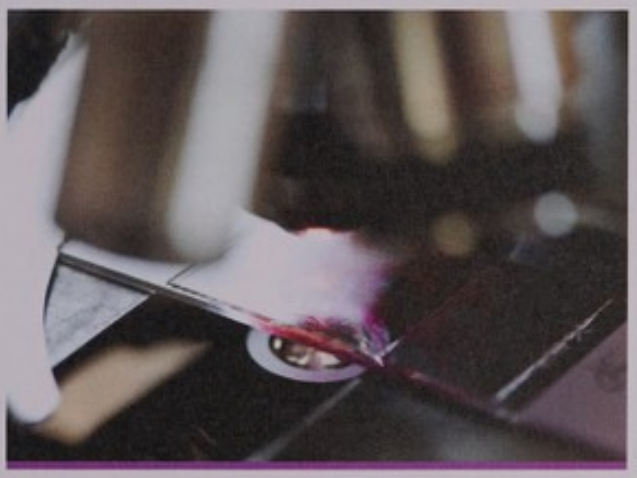
MARK PITT

CONSULTANT HISTOPATHOLOGIST
ROYAL PRESTON HOSPITAL, LANCASHIRE TEACHING HOSPITALS NHS FOUNDATION TRUST

"I AM A DESIGNATED INDIVIDUAL at the Royal Preston Hospital in Lancashire, where I am responsible for activities under the HTA licence and in relation to the retention of tissue following a hospital or coroner's post mortem.

"The communication links between the pathologist, laboratory, coroner and coroner's officers is vital. This is because the consent provisions of the Human Tissue Act 2004 for storage and use of tissue apply after the coroner's authority has ended and the fate of the tissue depends on the relatives' wishes. To make this process work more efficiently, we have nominated staff to officially liaise between the coroner's office, laboratory and pathologists – one in the laboratory and one in the coroner's office.

"The HTA's guidance was consistent with this process and gave it substance; it includes advice that all post mortem establishments put in place a 'nominated person', whose job it is to aid communication between those involved. In consultation with coroners,



pathologists, mortuary managers and the Ministry of Justice, the HTA developed a model communication flowchart.

"The HTA has recognised that the legal framework is complex and can be challenging and has sought to develop advice and guidance for those who have to implement and work with it."

IN OCTOBER, the HTA held its first conference for professionals working in the post mortem sector, where we launched the new communication flowchart, which helps ensure the wishes of relatives of the deceased in relation to tissue are acted upon.

Throughout the year, we continued to take appropriate and proportionate regulatory action across the sectors in response to non-compliances identified during our inspection and investigation processes.

We issued a regulatory alert to the post mortem sector, on compliance reporting and the retention of tissue and organs following post-mortem examination. We published an updated model consent form on our website, providing a suggested format for organisations obtaining consent for post-mortem examination of adults, in line with the requirements of the Human Tissue Act 2004. We also held meetings with coroners, pathologists and anatomical pathology technologists, consulting with them on key work.

For each of the sectors we license and inspect, we published a summary of compliance report. The reports provide an update of our activity in each sector and the extent of regulatory compliance.

In the forthcoming months, we will be gathering information from post mortem sector establishments to review their compliance with HTA standards, so that we can target resources to those that require support.

The HTA IN NUMBERS

SUMMARY OF THE HTA'S OPERATIONS IN 2009/10

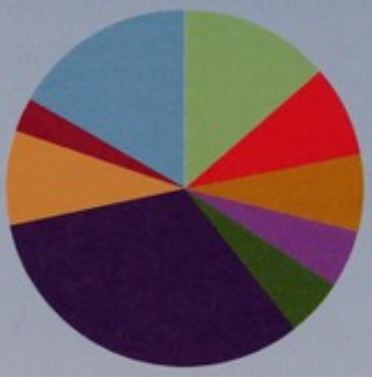
INCOME	£000s
Licence fee income:	5,328
Other income:	139
Government Grant-in-Aid:	1,133
Total Income:	**6,600**

EXPENDITURE	
Staff costs:	3,290
Operational and administrative costs:	2,735
Total expenditure:	**6,025**

NOTE: This is a summary only. The HTA's full Annual Report and Accounts are available at www.hta.gov.uk/publications/annualreviewsandreports.cfm

ALLOCATION OF HTA RESOURCES 2009/10

The chart below shows the breakdown of the HTA's expenditure in 2009/10. Donation approval, corporate work and part of accommodation costs were funded by Grant-in-Aid. The remaining categories were funded by licence fees.



- Site-visits
- Direct licensing activity
- Advice and guidance
- Policy and reporting
- Communications and media
- Licensing support costs (e.g. IT, staff recruitment and training)
- Accommodation costs
- Approval of organ or bone marrow donation
- Corporate work

6,500 e-newsletter subscribers

HOW MANY ESTABLISHMENTS DID WE LICENSE?

Number of licensed organisations by sector in 2009/10

Post mortem	Main site: 224	Satellite: 70
Human application	Main site: 185	Satellite: 87
Research	Main site: 144	Satellite: 92
Anatomy	Main site: 34	Satellite: 13
Public display	Main site: 15	Satellite: 3
TOTAL	602	265

NOTE: Satellite sites are premises operating under the same governance and supervisory arrangements as the main site.

HOW MANY ORGAN AND BONE MARROW DONATIONS FROM THE LIVING DID WE APPROVE?

Number of living organ donations: *(8% increase on previous financial year)*	1,140
Number of bone marrow donations: *(44% increase on previous financial year)*	78
Number of altruistic organ donations:	23
Number of paired organ donations:	12
Number of pooled (three-way exchange) organ donations:	4

HOW MANY INSPECTIONS DID WE CARRY OUT?

Number of phase 1 (desk-based) inspections:	51
Number of phase 2 (site-visit) inspections:	189

COMMUNICATION IN 2009/10

Website hits:	4,890,000
Individual visitors to website:	177,000
E-newsletter subscribers:	6,500
Number of enquiries since May 2009: **of which 10% were media enquiries*	3,890*

The YEAR AHEAD

During 2010/11 we plan to:

1. Operate a regulatory system for the removal, storage, use and disposal of human tissue and organs that is clear, consistent and proportionate

- Continue to fulfil our regulatory remits under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007
- Ensure the HTA meets its duties as a Competent Authority for tissues and cells
- Provide advice and guidance according to our statutory remit
- Carry out all activities in relation to consent and organ donation
- Aim to regulate in the most effective and efficient way, becoming more transparent, accountable, proportionate, consistent and targeted

2. Work with those we regulate and the public

- Capture and evaluate opinion on a number of issues, including consultation on a new licence fee structure
- Increase public awareness of the HTA
- Continue to manage the reputation of the HTA effectively

3. Be informed, influential and active in the environment in which we operate

- Develop more effective horizon-scanning and knowledge management arrangements
- Engage with key individuals and organisations to develop forward thinking and planning on policy issues associated with the five licensable sectors, consent and organ donation

4. Have motivated and dedicated staff with the right tools in the right jobs

- Recruit, lead and motivate staff to deliver high-quality work
- Deliver a high-quality learning and development programme
- Develop an environment which encourages continuous improvement and upholds the HTA's values

5. Continue to improve the way the HTA is governed and managed

- Further develop governance arrangements
- Review systems, processes and procedures to find ways of working even more economically, efficiently and effectively
- Ensure the continued financial viability of the HTA

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