

**Supporting change,
progress & innovation**
/Human Tissue Authority
Annual Review 2014-15



Welcome



I am pleased to be able to introduce this year's annual review publication, *'Supporting Change, Progress & Innovation'*, which focuses on the year's developments and how we intend to build upon our decade of expertise.

During 2014/15 – my first full year as Chair of the HTA – I have met extensively both with the organisations we regulate, and the people affected by our work. It is clear from those discussions that the HTA's remit remains as important and necessary as ever before. We are recognised as an effective and expert regulator – a great foundation on which to build.

However, we know our work is not yet complete. We continue to focus on improving standards by providing advice and guidance to professionals and the public, and by taking regulatory action in the small number of cases where it has been necessary. We have used our decade of expertise to influence legislation and policy, and to seek ways to reduce unnecessary burdens on the organisations that we regulate, particularly where the risks to the public are low.

We are a small, expert organisation, focused on quality. But high standards cannot come about by the efforts of the regulator alone. None of this work would have been possible without collaboration with those we regulate, industry, charities, professional associations, and government bodies. I thank them for their continued support for our work.

I would personally like to thank our outgoing Chief Executive, Dr Alan Clamp, for his hard work, commitment and continuous support over his five years with the HTA.

Under Alan's leadership, the HTA has successfully navigated through a great deal of change, while maintaining its commitment to public and professional confidence in human tissue regulation.

I would also like to thank outgoing Board Members, and to welcome our new Members, who bring both relevant professional expertise and great wisdom to our work.

In the decade since the HTA was created, we have achieved a lot. But there is more to do, and we are not complacent. Our 2015-18 strategic plan reflects how we intend to strengthen our expertise and keep abreast of the rapidly changing scientific landscape.

We will continue to improve public engagement in our work and public confidence in the safe use of tissue and organs, and to uphold our commitment to further reducing regulatory burden where it is safe and proportionate to do so.

Thank you.

A handwritten signature in white ink on a dark purple background. The signature is stylized and appears to read 'S. Nebhrajani'.

Sharmila Nebhrajani OBE
Chair, Human Tissue Authority

About the Human Tissue Authority (HTA)

The HTA is the regulator for human tissue and organs.

We make sure that the removal, storage, use and disposal of tissue and organs is undertaken safely, ethically, and with proper consent.

We monitor and inspect over 850 HTA-licensed premises against a set of standards.

We also assess over 1,200 organ and bone marrow donations from living people every year.

Through this work, we sustain public and professional confidence in the use of tissue and organs.

Improving standards



We have continued to improve standards in organisations that use tissue and organs for research, patient treatment, transplantation, teaching, public display and post-mortem examinations.

See pages 6-9.

Advice and guidance



We have continued to provide advice and guidance for professionals and the public.

See pages 16-17.

Our work during 2014/15 has focused on a number of different areas...

Influencing policy & legislation



We have been influencing EU and UK legislation and policy.
See pages 10-11.

Assessing donations



We have continued to assess donations of organs and bone marrow and peripheral blood stem cells from living people.
See pages 14-15.

Reducing burden



We have reduced unnecessary burden for the establishments that we regulate.
See pages 18-19.

Regulatory impact and looking ahead



We have been focusing on the regulatory impact of advancing science and technology.
See pages 20-22.

Improving standards

The HTA's regulatory activity helps to improve standards and increase public confidence in the areas that we regulate.

We continue to see good compliance with our standards across sectors and so our focus is on maintaining the significant improvements we have seen in practice.

This year, we conducted 210 site visits, including 139 routine inspections, where HTA Regulation Managers meet with staff in the organisations we license and evaluate their facilities against HTA standards. In 44% of cases, organisations met all of the HTA's standards.

The number of routine inspections which found instances of standards not being met increased slightly from 48% last year, to 56% this year. As in the previous two years, none were judged as critical (posing a significant risk to human safety or dignity, indicating a breach of legislation, or systemic failure).

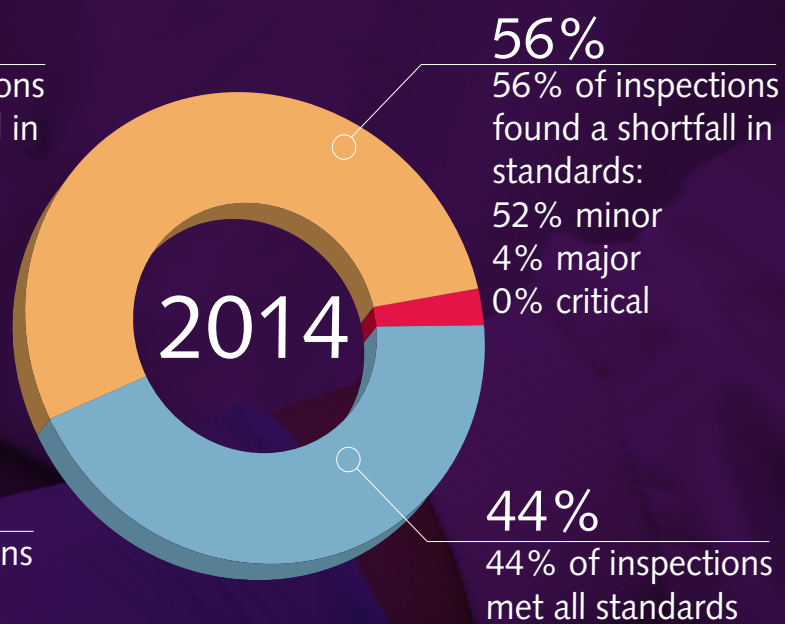
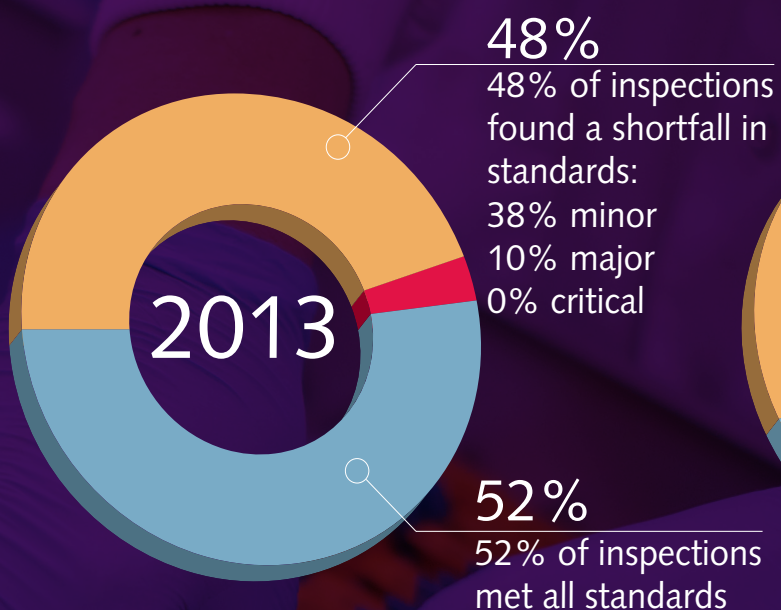
Four per cent of inspections found major shortfalls (those that pose a risk to human safety or dignity, indicate a failure to carry out satisfactory procedures, or breach our Codes of Practice), down from 10% last year.

Fifty-two percent of inspections found minor shortfalls (that indicate a departure from expected standards).

When organisations fall short of our standards, we work with them to draw up a plan for improvement. This year, we oversaw the delivery of 75 plans, which are usually completed within three months of the inspection.

We continue to receive information from members of the public and professionals about organisations indicating that there may be a breach of HTA standards. This led to six investigations and eight non-routine site visits.

Listening and responding to those who have concerns about organisations is an important way that we create robust regulation and enhance confidence.



90% of respondents answered 'yes' to the post-inspection survey question, 'Has the inspection process helped improve the way your organisation works?'

"As this was our first inspection, I was very pleased to hear feedback. Comments and advice were extremely useful and I am positive we will use these to further improve our service."

- inspection feedback



Serious incidents, events and reactions

The HTA helps to ensure the dignity of the deceased, and the quality and safety of patient treatments, by requiring all organisations we license in these areas to report issues to us when they occur.

Mortuaries must report serious incidents, such as release of the wrong body, or major equipment failure, within five days of the incident being discovered.

This year, there were 99 serious incidents in mortuaries, a slight reduction compared to last year. Although this is a small proportion of the 223,841 deaths reported to coroners and the 89,875 post-mortem examinations undertaken in 2014, each incident was carefully investigated.

Organisations that use tissue and cells for patient treatment are required to report to us any possible issues with the quality and safety of those treatments, within 24 hours of discovery.

In 2014/15 there were 14 serious reactions to treatments, a reduction compared to last year, and 80 serious events, such as the contamination of tissue, again a reduction on last year.


When these issues are reported to us, we require the organisation to conduct a full internal investigation which is then submitted to us for review. We make sure that the issue has been handled correctly, processes are changed if necessary, recommendations are made and followed, and that training takes place to reduce the possibility of the incident happening again.

We also use these incidents to share knowledge across our licensed organisations through the advice and guidance we give. Helping one establishment learn from another is an important way we improve standards.

Where we identify reoccurring issues with organisations, we take action. For example this year we identified inaccuracies or potentially misleading information in public-facing material published by private tissue banks.

We requested all such organisations to audit the information they publish, before we conduct a full independent audit of their materials later in 2015.

Using examples from across the organisations we license, we have also offered guidance to supplement our standards.



“Our experience of inspection was very positive, with two inspectors visiting each of our sites over four days. We have also recently put in place a new DI, the process of which was straightforward.”

- Oxford Radcliffe Biobank, University of Oxford

This includes information for mortuaries on the marking of bodies, training porters on mortuary procedures, model agreements with funeral directors on the movement of bodies, and contingency arrangements during busy periods.

We have offered information to organisations using cells and tissue for human treatments about storage, and updated these organisations on European legislation and standards.

Organisations licensed for organ donation and transplantation, such as Transplant Centres, are required to report any issues that may impact on the quality or safety of organs used in transplantation.

The system for reporting issues is managed by NHS Blood and Transplant (NHSBT) on our behalf. We review these issues with NHSBT every two months, to discuss the

management, investigation and reporting of incidents. This year, there were eight serious reactions to transplantations, and 17 serious events, such as damage to an organ.

Authorising tissue processing

All organisations licensed by us to develop patient treatments using tissue and cells are required to have an HTA-approved Preparation Process Dossier (PPD) if they wish to undertake the processing of a new type of tissue, or if they intend to make a significant change to an established process.

We use PPDs to ensure that establishments comply with EU law, which states that the establishment must not use processing steps that render the tissues or cells clinically ineffective or harmful to the patient. This year we authorised 28 PPDs.


Reviews of HTA inspections and audits

This year, the HTA published a review of the site inspections and site audits of organisations that hold either an anatomy licence or an organ donation and transplantation licence.

In May 2014, the HTA completed its first cycle of site inspections of the anatomy sector, which includes organisations such as medical schools.

In January 2014, we completed our first cycle of audits in the organ donation and transplantation sector, which includes hospital Transplant Centres.

These two publications summarised our findings, set out examples of good practice, shared successes, and offered practical support.



"We have continued to enjoy a very productive and effective relationship with the Human Tissue Authority in 2014/15. As we prepare for the introduction of the Human Transplantation (Wales) Act in December 2015, the invaluable support of the HTA to the implementation project has been very much appreciated. We look forward to continuing to work with you in the coming months."

- Dr Chris Jones, Deputy Chief Medical Officer, Welsh Government

Influencing policy & legislation

The HTA uses the knowledge gained over ten years of regulation to inform UK and European policy and legislation.

This year, we used our knowledge about the quality and safety of organs and tissue to inform the House of Commons Science and Technology Committee inquiry into blood, tissue and organ screening.

Our knowledge about living organ transplantation helped us to inform a National Institute for Health and Care Excellence (NICE) consultation into living donor liver transplantation, and a UK Donation and Ethics Committee consultation into donation after brainstem death.

We used our experience of assessing donations from family members living overseas to inform the Parliamentary committee drafting the Draft Modern Slavery Bill.

We continue to offer guidance to the Welsh Government and the UK Government ahead of the introduction of the Human Transplantation (Wales) Act 2013, which will introduce a 'soft' opt-out system for consent to deceased organ and tissue donation in Wales in December 2015. We published a revised code of practice for medical professionals in 2014.

We offered expert advice to the Government's Regenerative Medicine Expert Group who develop the NHS regenerative medicine

strategy, which ensures that the NHS is fully prepared to deliver innovative treatments. The group investigated the effect of regulation on the development of regenerative medicines in the UK.

The HTA has played an active role in the group and, alongside other regulators in this area, has further streamlined the regulatory pathway for manufacturers of advanced therapy medicinal products.

In March 2015, the All-Party Parliamentary Group on Stem Cell Transplantation published '*Cord Blood Transplantation: Meeting the Unmet Demand – Progress Review*'.

The report recommends that Antony Nolan, NHSBT and private cord blood banks, work with the HTA to ensure women are fully equipped to make an informed decision about cord blood banking.

Contributing in Europe and beyond

In March 2015, the HTA attended an EU meeting on organ trafficking, which included the signing of the convention against trafficking.

The convention aims to prevent and combat the trafficking of human organs, protect the rights of victims, and facilitate co-operation

at national and international level.

We have participated as experts on two EU working groups responsible for drafting two new European Directives on Coding and Import. The Directives build on existing legal requirements by adding technical detail on how those requirements should be met.

The Directives will ensure more consistency across the EU on the coding and importing of tissues and cells, which in turn will result in improvements to traceability and vigilance as well as to the monitoring of the quality and safety of imported tissues and cells.

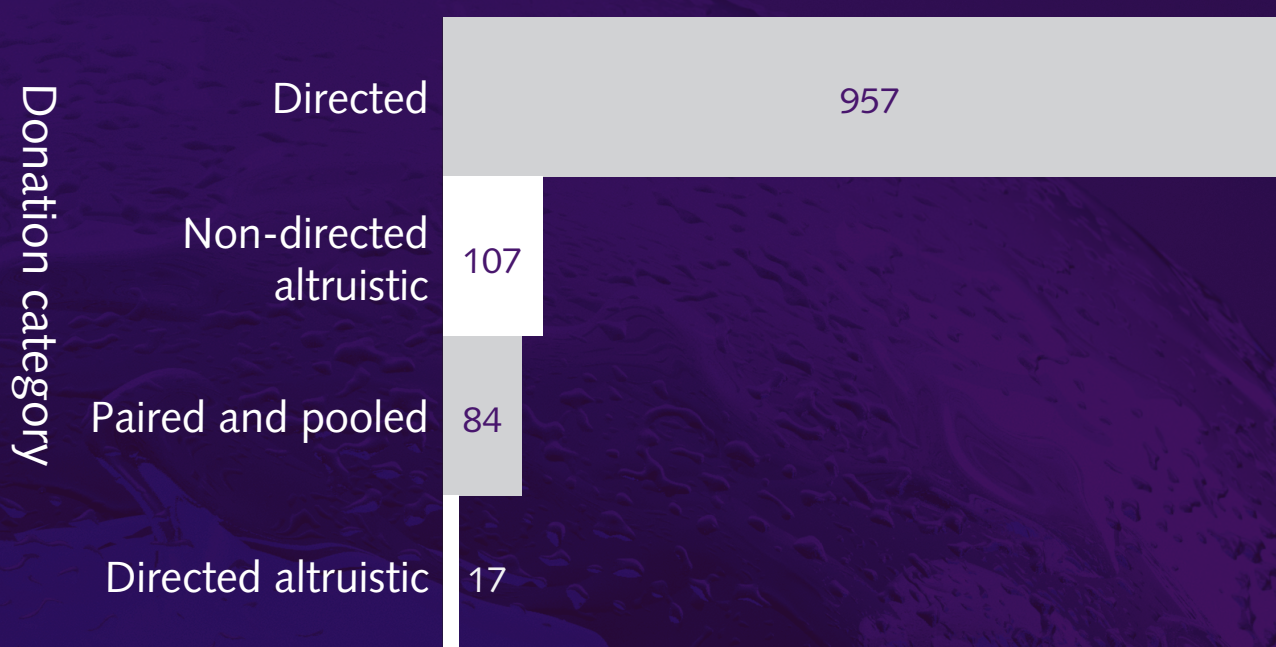
The HTA is currently working with the government on the transposition of the Directives into UK law.

We have also worked with the US Food and Drug Administration and the American Association of Tissue Banks to develop a tool for US exporters and UK importers which will support establishments in ensuring that tissues and cells imported into the UK meet UK standards of quality and safety.

Our year in numbers

Living donation assessments

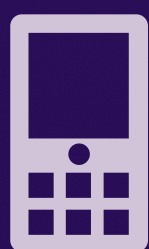
1,165 living organ donation assessments



Licensing

852 licensed premises
24 licence applications

Enquiries

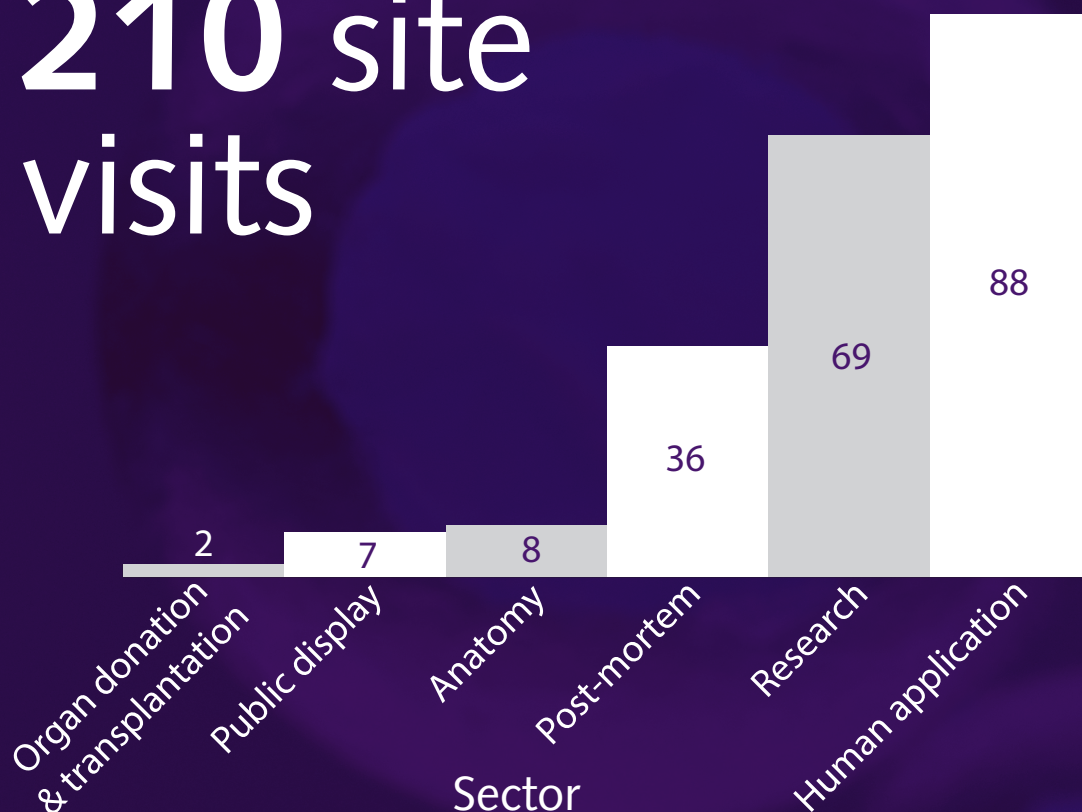


1,000 professional enquiries

1,200 public enquiries

Inspections and investigations

210 site visits



139 routine inspections

8 non-routine inspections

75 improvement plans (CAPAs)

6 investigations

193 investigations into serious incidents, events and reactions

HTA people



48 staff

11 Board Members

129 Independent Assessors

54 Accredited Assessors

510 Designated Individuals

Assessing donations

While most transplanted organs are donated from people who have died, every year more and more people receive organs from living donors. Now, nearly half of all kidney donations are from living donors.

Since 2006, the HTA has assessed each and every organ donation from a living person in the UK to make sure that valid consent has been given, that no reward has been sought or offered, and that risks have been explained and understood.

This year we assessed 1,121 living kidney donations. Of these, 106 were instances of people altruistically giving kidneys to people they did not know, and 17 were instances of people giving an organ to someone that they had no prior relationship with – for example, someone they might have found through a local newspaper article. We also assessed 44 living liver donations.

“To see a donor giving a part of him or herself for the sake of another is a humbling experience. To hear their stories is a privilege. To be a small part in their journey is uplifting.”

- Independent Assessor

We currently have 129 Independent Assessors (IAs) who are trained to carry out interviews with the organ donor and the recipient on our behalf.

They look for evidence to make sure that valid consent has been given, no reward is sought or offered, and that risks are fully explained and understood.

This year, we went through a process of reaccrediting all IAs, ensuring that they are trained for the sensitive role they carry out and that high report-writing standards are maintained.

We also issued guidance to IAs on carrying out and recording recipient interviews, ensuring proof of identity and evidence of relationship, dealing with referral letters and donor declarations, and preventing duress, coercion and reward.

Social media continues to enable people to share stories, seek donors, or offer donations. We continue to review our existing guidance to cover these circumstances, and agree and share best practice.

A clear trend in the living organ donation cases that we assess is their increasing complexity. We have seen a rise in the number of donors from overseas, and more cases where the donor and recipient did not have a pre-existing relationship.

We continue to work with IAs and those working in Transplant Centres on the particular complexities of such cases.

Revised guidance to transplant teams and Independent Assessors

Our formal ‘*Guidance to transplant teams and Independent Assessors*’ was revised comprehensively this year. It now contains more detailed information on organ trafficking and the signs that the clinical community should look out for to prevent it, the evidence needed to prove relationships, how to explore further when facts appear not to match, and comprehensive interview and report writing techniques covering sensitive topics.

Bone marrow and peripheral blood stem cell donation

We assess bone marrow and peripheral blood stem cell donations from children and adults who lack the capacity to consent. This year we assessed 69 such cases. We train Accredited Assessors to support our work in this area.



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assessed...

1,121
living
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44
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69
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stem cell
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Advice and guidance



The HTA provides advice and guidance to help support organisations to meet our standards and improve their practice. The feedback we get from the organisations we regulate shows consistently that they value the guidance we offer.

Events, meetings and workshops

This year we have continued to hold events, workshops and meetings across the sectors we regulate.

In March 2015, we held three well-attended workshops for those working in the post-mortem sector. Over 150 individuals attended from across 70 HTA-licensed organisations, including pathologists, anatomical pathology technologists, bereavement midwives,

police officers, and biomedical scientists.

Our advisory groups – the Histopathology Working Group, the Transplant Advisory Group and the Stakeholder Group – continue to meet twice yearly.

These meetings are an important way for people working in the organisations we regulate to inform, engage in, and contribute to our work.

The HTA's July 2014 annual event and public authority meeting was attended by over 100 sector experts. The event

"The Anatomical Pathology Technologist (APT) profession has undergone vast change during the time the HTA has been in existence. It has benefitted greatly from the advice, guidance and support the HTA has provided."

- Mortuary & Coroner Support Manager

focused on the importance of public confidence, and how we can all work towards increasing public engagement and involvement in our work.

Members of the HTA Executive also attended and spoke at a number of events over the last year, such as the 2015 British Transplantation Society conference, and the 2014 Association of Anatomical Pathology Technology conference.

Providing information

This year, we produced a great deal of guidance to help the

organisations we regulate. Through our e-newsletter, we provided information on cost recovery and consent forms for the research sector.

We also refreshed the information we provide on consent and the use of DNA, and mapped our standards for the post-mortem sector against those of the Royal College of Pathologists.

We contributed to Hospice UK's revised national guidance on care after death, which aims to ensure there is well co-ordinated support after someone has died and that the wishes of the deceased and their families are respected.

We worked with the Medical Research Council's Regulatory Support Centre to update their research and human tissue legislation

of new national guidance for hospitals and abortion clinics on the sensitive handling of pregnancy remains.

HTA Codes of Practice

In 2014, we updated each of our nine Codes of Practice to reflect recent policy decisions and legal advice. These amendments were made ahead of a full-scale review and consultation of the codes, which will take place in 2015/16.

Information for the public

This year we strengthened our focus on engaging members of the public who are interested in our work.

We redeveloped the HTA's website to offer a stronger focus on public information, including information about body, brain and tissue donation, and living donation.

We ran a survey, asking for views from members of the public who had donated their cord blood, or who were thinking about donating their cord blood. The results of the survey clearly showed a need for more information in this area.

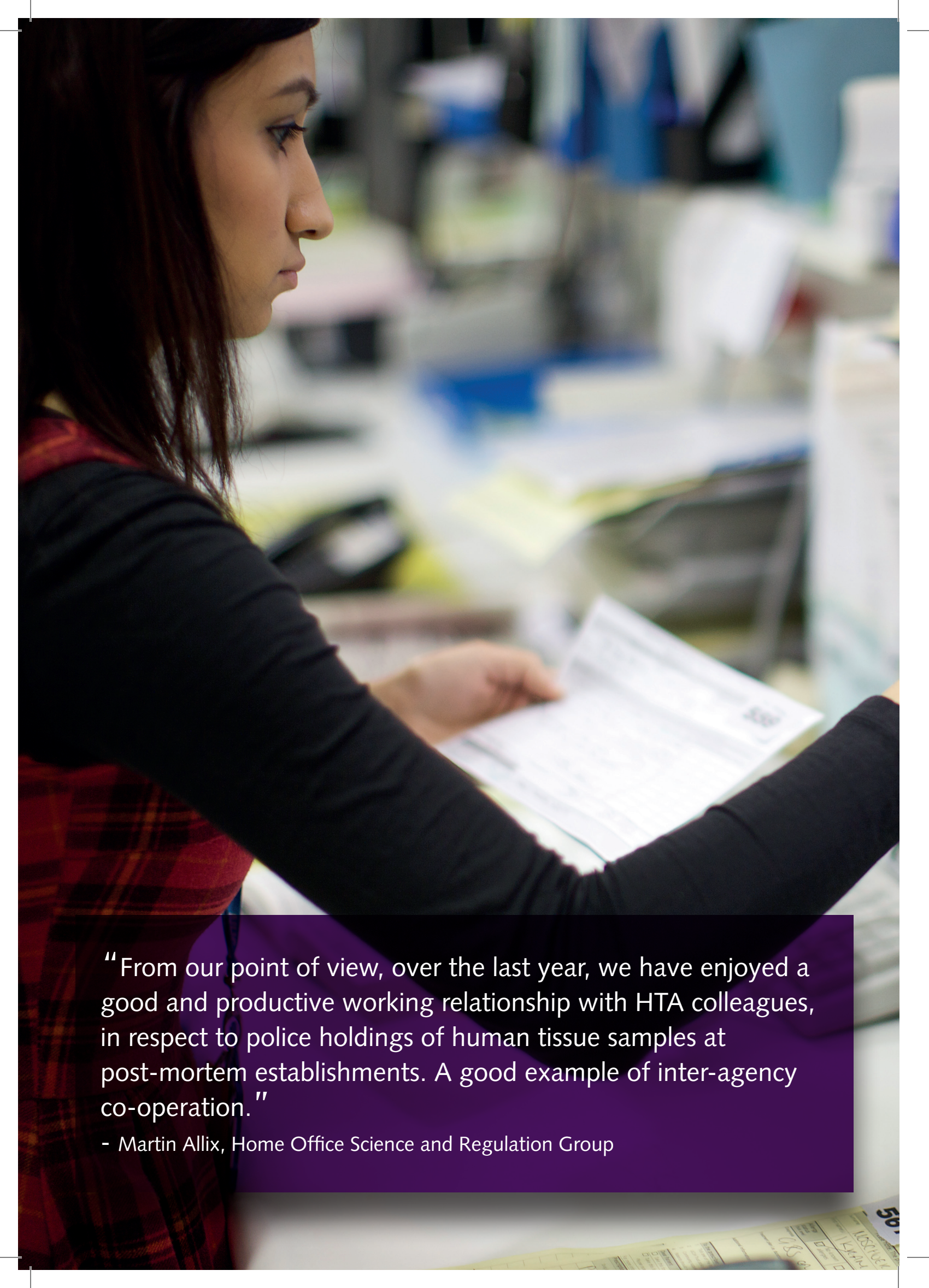
As a result, the HTA will be developing a new package of information about cord blood donation for the public in the coming year.

"Lots of excellent advice which we will take forward and use to improve the service."

- inspection feedback

summaries on consent and licensing, making sure our guidance is represented accurately no matter where researchers find it.

We also worked with a range of experts in the development

A woman with long dark hair, wearing a black long-sleeved shirt and a red and black plaid vest, is shown in profile, looking down at a document she is holding. The background is a blurred laboratory or office environment with various equipment and papers. A purple semi-transparent box is overlaid on the bottom right of the image, containing a quote and the name of the speaker.

"From our point of view, over the last year, we have enjoyed a good and productive working relationship with HTA colleagues, in respect to police holdings of human tissue samples at post-mortem establishments. A good example of inter-agency co-operation."

- Martin Allix, Home Office Science and Regulation Group

36%
reduction in
licence fees
since 2010

Reducing burden

The HTA strives to be an exemplar of modern regulatory practice.

We want to see the establishments we license helped, not hindered by our work.

Ultimately, our goal is very similar to the establishments we license – to support the future of UK healthcare and to protect the public.

We are constantly reviewing our work and practices to make sure that we are not placing unnecessary burden on those we regulate.

With these principles in mind, this year, we assessed ourselves against the Better Regulation Delivery Office's Regulators' Code. The results, which we published, show how we: support the organisations we regulate to comply and grow; engage with our partners; are risk-based and share information; offer advice and guidance; and ensure that our approach is transparent.

Along with our self-assessment, we published an action plan outlining how we intend to improve even further in this area. This work has been recognised as good practice by the Better Regulation Delivery Office.

In July 2014, a year after Justin McCracken published his independent efficiency review, the HTA demonstrated that we had addressed the seven recommendations set out for us.

In addition, we have been able to set the 2015/16 licence fees to bring in a similar level of income to the previous year. Overall, since 2010, there has been a 36% reduction in HTA licence fees.

Joint inspections with UKAS

The HTA has been working with the United Kingdom Accreditation Service (UKAS) to reduce regulatory burden for post-mortem sector establishments with UKAS accreditation by developing a joint inspection

process. This year we conducted six joint site visit inspections, with more to be scheduled in 2015/16.

We also delivered training to UKAS assessors on the Human Tissue Act and on our inspection process, aligning UKAS standards with ours. Our work with UKAS has been formalised by a Memorandum of Understanding.

Regenerative medicine advice service

In October, we launched the regenerative medicine advice service in collaboration with the Medicines and Healthcare products Regulatory Agency, the Human Fertilisation and Embryology Authority and the Health Research Authority.

The advice service aims to support those working in the innovative field of regenerative medicines. The service provides a single point of access to advice from the

four regulatory bodies involved in regenerative medicine.

The initiative was met with widespread support at launch. A review of the service is planned in the coming year.

Sharing information about research

Human tissue research that takes place with recognised research ethics committee (REC) approval is exempt from HTA licensing. However, it is common for establishments working with REC approvals to also hold a storage licence for other research.

During HTA inspections, we focus on human tissue that is stored under our licence, but also seek to understand how systems are used to manage tissue that is stored with REC approval.

This information can be shared with our colleagues at the Health Research Authority to further reduce burden.



Focusing on regulatory impact

At the HTA, we understand the need not only to regulate well now, but to keep a focus on the future.

Science moves with great pace, and our challenge is to make sure our regulation fits the developing activities within our licensed sectors, in a way that helps establishments grow and improve.

This year we continued to support the work of the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs). The NC3Rs collaborates with scientists and organisations from across the life sciences sector.

By working with NC3Rs and advising on our regulatory framework, the HTA is helping researchers to move from research involving animals to research using human tissue.

We have also provided advice and support to a number of initiatives that aim to promote good biobanking practices.

One such initiative is improving access to research material by making stored research tissues more discoverable to researchers, for example, through the newly-established UK Clinical Research Collaboration Tissue Directory and Coordination Centre.



We continue to improve because we seek, and take on, feedback from the professionals working in licensed organisations and members of the public who are affected by our regulation.

This year, we surveyed these audiences on: the HTA's new website; cord blood information; revised PPD guidance; and the HTA's strategic direction.

We ask for feedback after every inspection of the establishments we license.

We also seek feedback from attendees after all HTA events, and workshops to make sure we are constantly improving.

97% of respondents providing post-inspection feedback rated the overall inspection process as either 'good' or 'excellent'.

Looking ahead

Next year will be another challenging one for the HTA, in which we aim to complete a number of significant projects.

We are reviewing our licensing and inspection processes and revising our Codes of Practice and standards.

We will also be consulting on the revised codes and the

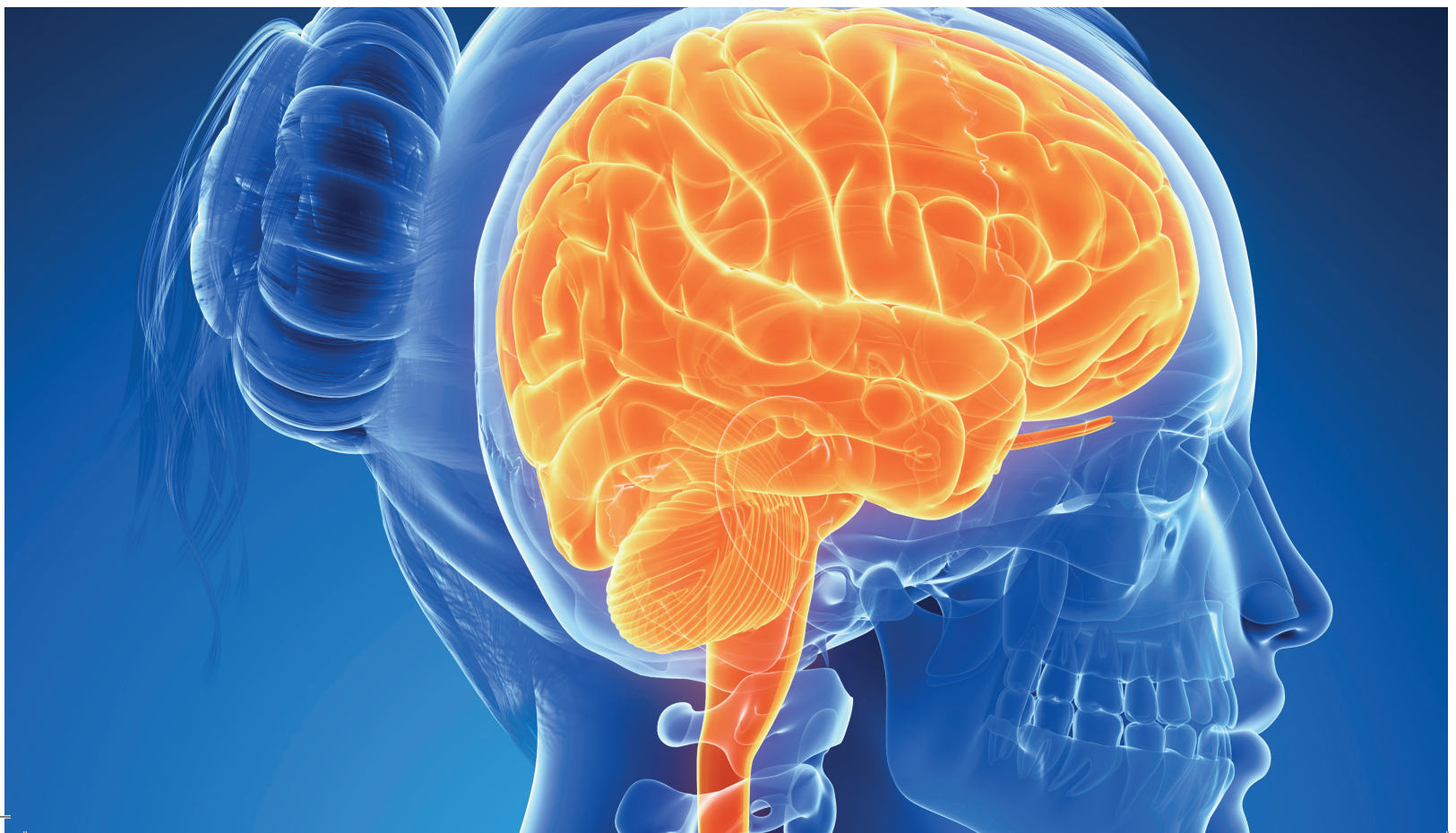
new EU import and coding legislation and reviewing how we sustain public confidence.

In December 2015, the new code of practice on the recently passed Welsh organ donation law will come into force.

We also plan to publish further guidance for professionals such as revised PPD guidance, and for the public on donation.

We will continue to look for ways of improving efficiency, and to support growth by deregulating where the risks are low.

It will be a challenging year and we have much to do. Throughout, the HTA will remain committed to ensuring the safe and ethical use of tissue and organs.



Our values

Transparency

"The auditors were very transparent, which was a big help during the audit, and the advice they gave was very informative and clearly explained."

Expertise

"The information provided was useful. The inspector was very knowledgeable and talked from a point of experience."

Respect

"Friendly, open and clear with excellent communication. It was a pleasure working with them."

"Excellent service is provided whenever it is required."

Excellence

"When unsure, they have always said so, rather than mumble their way out. This is comforting and commendable."

Integrity

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