

New science, new challenge

Annual Review
2015-16

 **HTA**
Human Tissue Authority



A message from our Chair

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I am extremely pleased to introduce the HTA's 15/16 annual review, 'New Science, New Challenge', which looks forward to some of the most exciting scientific developments in the sectors we regulate, as well as reviewing our work over the last 12 months.

The year has been another busy one for the HTA. We have continued to develop a regulatory approach that responds to the accelerating pace of scientific developments while preserving our core principle; that human tissue and organs should be stored and used safely, ethically and, above all, with consent.

This is no mean feat; our legislation is over 10 years old. At the time our legislation was being developed, we could not have conceived of the many scientific and technological advances we see today, or the myriad applications for which they might be used. From the use of stem cells in regenerative medicine to novel forms of transplantation, new treatment possibilities are emerging and new businesses are being created.

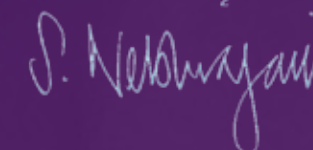
In the context of the UK as a world leader in science and innovation, we recognise our dual responsibility to ensure the safety of these activities for the public, while supporting that innovation and the resulting future economic growth.

This year we continued to work within our legislation to respond flexibly and appropriately. We have offered guidance on how emerging technologies, like non-invasive post-mortems, fit with our regulatory framework. We have brought private tissue banks together to discuss standards. We have identified where we can conduct joint inspections to reduce burden. We have published an innovation plan and contributed actively to the Government's burden reduction agenda, looking specifically at the small businesses that we regulate. We also designed and consulted on a new set of Codes of Practice and Standards that more closely reflect both new science and practices in the organisations we license. These will launch next year.

None of this would have been possible without collaboration between HTA staff, those we regulate, industry, charities, professional associations, and government bodies. I would also like to offer my personal thanks to our expert HTA staff and our Board Members old and new, many of whom are also experts in the fields we regulate. I would like to thank them for their continued support for the important work of the HTA.

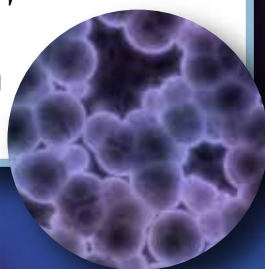
I look forward to developing our collaborations further to ensure confidence in the safe and ethical use of human tissue and organs. As well as supporting the delivery and development of high quality services and treatments for individuals and their families.

Thank you.
Shar



Our year in highlights

Milestone for Regulatory Advice Service for Regenerative Medicine: Six-month anniversary of the Regulatory Advice Service for Regenerative Medicine. The cross-regulator advice service offers a single point of access to free, clear, expert responses to queries about the regulation of regenerative medicines.

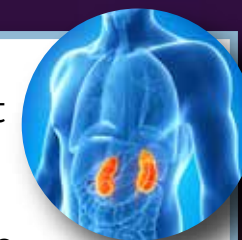


New agreement with UKAS: The United Kingdom Accreditation Service (UKAS) and the HTA signed a joint working agreement to further reduce burden for those mortuaries with an HTA licence and UKAS accreditation. This agreement outlines a framework for joint work, including conducting joint inspections.



Increased interest in body donation: Following media coverage, the HTA saw a huge increase in the number of calls we received from people interested in donating their body for medical research. We gave over 600 people information about body donation and told them how to contact their local medical school.

New Welsh organ donation law: The new Human Transplantation (Wales) Act 2013 came into force in Wales. This new law creates an opt-out system of organ and tissue donation for adults who live and die in Wales. The HTA published a Code of Practice which offers practical advice to professionals working under the law.



Parents' guide to cord blood banking: We published a cord blood banking guide for parents considering cord blood donation or banking. The guidance aims to support parents to make an informed choice about cord blood. Over 1,000 people have looked at this guide on our website since it was published.



Government review of the HTA: As part of a regular triennial review cycle, the Government reviewed the HTA and its functions. Partner organisations were asked for their views on the role and performance of the HTA. The review and the HTA's response will be published later in 2016.



June

August

October



December

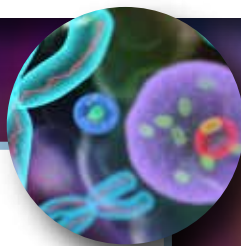
February

2015

2016

May

New bone marrow and stem cells guidance: The HTA published revised guidance on the regulation of bone marrow and peripheral blood stem cell donations when the donor is an adult lacking capacity or a child without the ability to consent. The guidance provides detailed information for professionals working in this area and aims to standardise practice.



July

September

HTA Codes of Practice and Standards consultation: The consultation on the HTA's revised Codes of Practice and Standards opened. Nearly 200 professionals and members of the public came to workshops. In addition, we received 97 written responses to the consultation.



November

Mortuary capacity and contingency report: We published a report on capacity and contingency arrangements in mortuaries across England, Wales and Northern Ireland. The report sets out some of the challenges that mortuaries face and includes recommendations for contingency storage capacity.



January

HTA public e-newsletter: We published the first edition of the HTA's public newsletter. This newsletter is aimed at members of the public and those working in public-facing organisations that are interested in our work.




March

Emergency planning for London: The HTA received excellent feedback for the role we played in an exercise to test London's ability to handle a large-scale emergency. We licensed an emergency mortuary, ensuring that even in these difficult circumstances, good standards of practice are maintained and the deceased are treated with dignity and respect.



10-year anniversary conference: Allan Marriott-Smith, the HTA's newly appointed Chief Executive spoke at the HTA's 10th anniversary review event, 'Supporting Change, Progress and Innovation'. Over 100 people were in attendance to discuss what might constitute informed consent and to inform the development of our Strategy.





The difference we make

We are a small, expert, well-respected regulator with diverse functions and a broad remit. We focus on raising standards and professional practice across all areas of our work. We work in collaboration with other organisations, providing advice, guidance and training. We ensure our approach is streamlined, allowing us to reduce burden without affecting public confidence.

Listening and changing

The HTA is constantly evolving based on the feedback we receive from those we work with, and this year was no exception.

We sought feedback from professionals about attitudes to brain and spinal cord donation, pathology collections and our policies on innovation and human T-cell lymphotropic viruses testing.

We received a great deal of input from the online consultation and events about our revised Codes of Practice and Standards. The HTA also convened three groups that support our work; the Stakeholder Group, Histopathology Working Group and Transplantation Advisory Group. These groups offer expert advice about HTA policy development.

We also sought feedback following every inspection, event and training course which will influence how we approach this work in the future.

Offering advice and guidance

Every year the HTA produces new or updated advice and guidance to help organisations to meet our standards and professionals to improve their practice.

This year, after collecting data from the post mortem sector, we published a report offering advice to mortuaries about their capacity and contingency arrangements.

We published a Code of Practice for professionals working under the new Welsh organ donation law and revised our guidance for those who assess the donation of bone marrow and peripheral blood stem cells from people who lack the capacity to consent.

In the research sector we revised guidance about research tissue banks. In the human application sector we worked with the Medicines and Healthcare products Regulatory Agency (MHRA) to produce joint advice on the regulation of blood as a starting material for ATMP manufacture and on the regulation of faecal microbiota transplants.

We also updated our Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment and our guidance on Preparation Process Dossiers. In the organ donation and transplantation sector we updated our guidance on reporting serious events and reactions.

Improving public understanding

We protect public confidence in the use of human tissue and organs. To support this work, we published new information to help the public make informed decisions about the use of their tissue and organs.

We published information on body donation alongside a new body donation card that donors can carry with them.

We published new information on brain donation, tissue donation, and cord blood donation. We also produced new guides to consent and deceased organ donation in collaboration with NHS Blood and Transplant (NHSBT).

All this guidance was published in the HTA's new public newsletter and distributed through organisations that have a direct link with the public. In the future, guidance like this will be developed with our newly established Public Review Panel.

Influencing across sectors

As a small organisation, we collaborate with others to raise standards across all of the sectors we work with. This year we contributed to training that the Care Quality Commission (CQC) and Association of Anatomical Pathology Technology (AAPT) provided for the professionals they work with. We also contributed to Coroners' Officers training.

We offered our expertise to the Health and Safety Executive (HSE) on working safely with cadavers, Hospice UK on care after death and the Royal College of Nurses (RCN) on pregnancy remains.

We also provided information to the Northern Ireland Assembly on their proposed organ donation law, to the Scottish Government on their proposed Cremation and Burial Bill and to the UK Government on regenerative medicine and reducing burden.

Reducing burden and supporting innovation

We are committed to working collaboratively to support innovation and further reduce burden while increasing public confidence. This year we published innovation and regulation and burden reduction plans. We also contributed to the consultation on the Business Innovation Target, Growth Duty and Small Business Appeals Champion. Where possible, we have worked within our legislation to support innovation and reduce burden.

We worked with the Human Fertilisation and Embryology Authority (HFEA), MHRA and Health Research Authority (HRA) to answer enquiries as part of the Regulatory Advice Service for Regenerative Medicine, and will be extending this approach to other areas of research.

We continued to look for opportunities to conduct joint inspections and this year signed an agreement with UKAS. We announced that the fees licensed organisations pay would be held steady for another year.

We have also offered guidance on how emerging technologies such as non-invasive post mortems fit with our regulatory framework and have stepped up our work with private tissue banks.

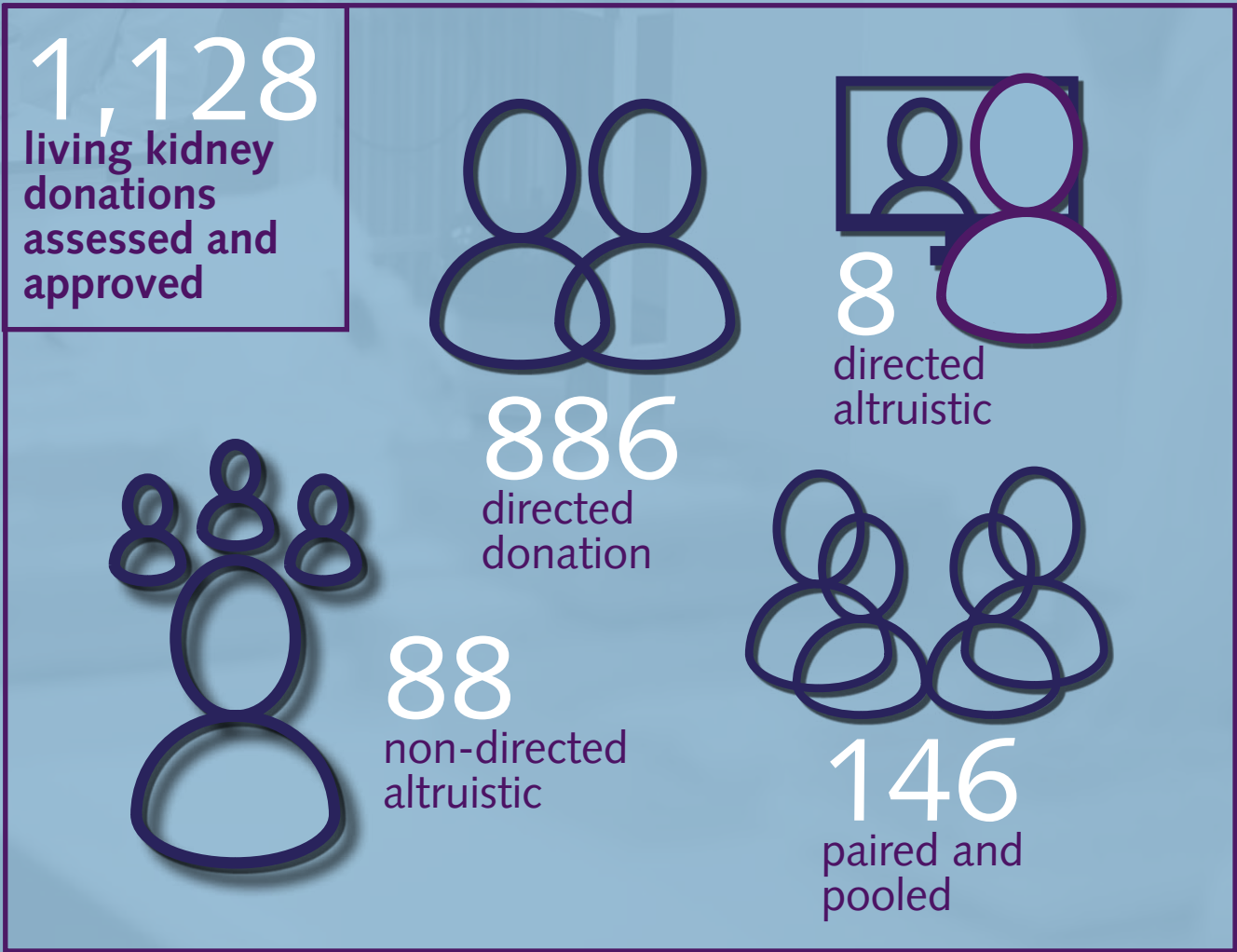
Assessing living donations

This year we made sure that 1,172 solid organ donations from living people across the UK took place freely and without coercion. We also made sure that appropriate consent was in place, that no reward was sought or offered and that the risks were explained and understood.

We assessed and approved 1,128 cases of living kidney donation this year. Eight hundred and eighty six were cases where someone was donating to a person that they knew (directed donation). There were also eight cases where someone was donating to someone they did not know personally (directed altruistic), for example having met after a social media appeal. This is in addition to 88 cases where someone was donating to a person whose identity they would never know (non-directed altruistic). Finally, there were 146 cases where a donor and recipient were incompatible, so they were matched with other pairs as part of a sharing scheme (paired and pooled).

We assessed and approved 42 cases where someone donated a part of their liver to someone they knew and two cases where they donated part of their liver to someone they did not know at all. We also assessed 55 cases where someone lacked the capacity or ability to consent to donate bone marrow or peripheral blood stem cells.

Of all of the cases, 238 were approved by a panel of HTA Authority Members. This includes all non-directed altruistic and all paired and pooled cases, as required by law.



Raising standards

We want to ensure all of the 861 sites we license meet our standards. This in turn will increase public confidence in the sensitive areas we regulate. This year we visited 234 licensed premises. Of these, 228 were routine site visits, 42% of which met all of our standards. Of those that did not meet our standards, 47% had minor shortfalls, and 11% had major shortfalls.

In addition to site visits, we assure ourselves that standards are met in other ways. For example, to oversee the sectors we regulate and inform the scheduling of inspections, 400 organisations licensed for anatomy, public display, research and post mortem provided us with information about their activities. Summaries based on the data we collected will be published later in 2016.

When organisations do not meet our standards, we work with them to develop an improvement plan (Corrective and Preventative Action plan). This year we put in place 101 of these plans, 68 of which have been closed. We are working with individual organisations to close those that are ongoing.

Occasionally we may conduct site visits for reasons other than a routine inspection; this might be because of concerns that have been raised about a licensed organisation or to follow up on a reported incident. This year we conducted three non-routine inspections. These resulted in one critical shortfall, two major shortfalls and six minor shortfalls. We also carried out three site visits to follow up on incidents that were reported to us.

Serious issues in the establishments we license are rare. This year 102 serious incidents in mortuaries were reported to us, which equates to about three incidents for every 10,000 bodies admitted. There were 19 serious reactions to patient treatments and 41 serious events reported to us by human application establishments and 14 serious reactions and 22 serious events reported to us by organ donation and transplantation establishments. When issues are reported to us, we make sure that the organisation conducts a full investigation. Following the investigation, we look at whether the incident was handled correctly, we make sure recommendations are followed, and lessons are learned across the sector.

Sites

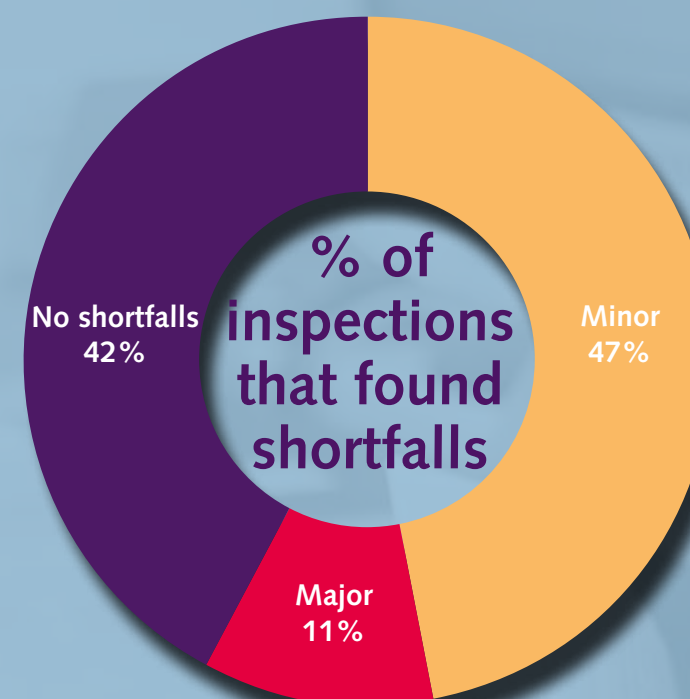


573 main sites licensed



288 satellite sites licensed

Shortfalls



Total shortfalls:

239 minor
26 major
0 critical



101 CAPA plans
(68 closed)



Incidents



60 serious events & reactions in human application

36 serious events & reactions in organ donation & transplantation



102 serious incidents in mortuaries



3 non-routine inspections

HTA people

528 Designated Individuals
46 Accredited Assessors
140 Independent Assessors
46 staff
12 Authority Members





Looking ahead

We know the HTA continues to be recognised as an effective, expert regulator. We have overseen significant improvements in the organisations we license and our remit and responsibilities have continued to grow.

This is an exciting time for the HTA. We face the triple challenge of regulating new scientific advances, supporting new business models using existing technology, and reducing regulatory burden where we know risk is lowest, all while maintaining public confidence in the use of human tissue and organs.

In April 2016, we published a new HTA Strategy that described how we intend to balance these challenges and opportunities. The Strategy identifies new business priorities as well as setting out a route map for how to deliver them. It also describes how we will deliver our day-to-day operations, develop a regulatory model to maintain public confidence and deploy our resources.

Alongside our Strategy, we also published our business plan for 2016/17. This highlights how we adapt to support innovation, reduce burden and increase public confidence.

- We will implement our revised Codes of Practice and Standards. This will introduce new working practices that reflect the high standards we expect organisations to meet
- We will continue to refine our regulatory model to focus on reducing burden where risks to public confidence are the lowest
- We will consult on a change to our fees structure and implement the changes for 2017/18
- We will continue to work with members of the public to ensure that we maintain confidence in our work
- We will undertake work with Designated Individuals at licensed establishments to build on the relationships we have with them

This is a large programme of development work for such a small organisation. However we are committed to delivering it, as ever, drawing on the wisdom and insight of our partners to support us.

Thank you
Allan



Your feedback

"The MRC Regulatory Support Centre values its partnership with the Human Tissue Authority, in helping us provide authoritative practical help to the research community" **(MRC)**

"The response from the HTA to the request for a licence for the emergency mortuary was effective and efficient. The HTA inspectors attended the scene promptly to assess the application and provide advice. The licence was swiftly granted, allowing the work of the mortuary to proceed without interruption and reassuring me that this was not an area of concern." **(Fiona Wilcox, HM Coroner for Inner London West)**

"I appreciate the fact that you took the time to listen to me and I'm sure other body donors will also be happy having a card that they can carry with them" **(Maureen Reynolds, member of the public)**

"It was of considerable help to hear Sarah Bedwell present on regulatory matters; a complex area made far clearer as a result of listening to them. This will be a great help to me in the future." **(Olivia Grant – Newcastle)**

"Caroline Browne from @HTA_UK did a wonderfully concise presentation at #CuratingHumanRemains in Bristol" **(Barts pathology)**

"We are extremely grateful to the HTA for playing a major role in helping us to secure financial investment to undergo a major re-development at our establishment following their inspection, so our facilities can allow clinical colleagues the opportunity to develop their knowledge and skills." **(Anatomy, Queen's University Belfast)**

"It is good to see that the HTA is continuing its tradition of being a pragmatic regulator" **(inspection feedback)**

"The HTA are supportive and open to suggestions for improvement, and this has made it easier for me to do the Independent Assessor role" **(assessor feedback)**

"We felt throughout that the HTA was working with us to deliver the best standards possible" **(inspection feedback)**

"Excellent support from the inspection team. The process was very professional, constructive, transparent and educational" **(inspection feedback)**

"The post-inspection discussion and co-operation is particularly appreciated." **(inspection feedback)**

"An excellent approach. The inspectors were very approachable and knowledgeable." **(inspection feedback)**

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