Issue 33 February 2012

Welcome to the February issue of the Human Tissue Authority's (HTA's) e-newsletter. The e-newsletter is the main way we communicate developments in regulatory policy and is essential reading if you work in one of the sectors we regulate or your work links to ours. We now have more than 7,000 subscribers. We also use the e-newsletter to let you know about new advice and guidance and important updates to our website.

This issue includes an update on the HTA's licence fees; an EU Organ Donation Directive consultation update, our response to the Welsh White Paper on an opt-out system for organ donation; and an alert to new authorisation requirements for processes in the sector that uses tissue and cells for patient treatment.

If you have any comments or queries about the issues raised in this e-newsletter, or any ideas for items that you would like to see in future, please contact us at: enquiries@hta.gov.uk.

EU Organ Donation Directive consultation update

As outlined in the October e-newsletter, the HTA consulted on the draft Documentary Framework for the Quality and Safety of Human Organs Intended for Transplantation. This consultation ran in parallel with the Department of Health's (DH) consultation on the draft Quality and Safety of Organs for Transplantation Regulations that transpose Directive 2010/53/EU on the standards of quality and safety of human organs intended for transplantation (the Organ Donation Directive) into UK law. Both consultations closed on Wednesday 21 December and the HTA is grateful for the useful responses received.

Respondents included: individual transplant centres; the British Transplantation Society; professional bodies such as the British Medical Association and the Royal Colleges of Pathology and Physicians; the British Society of Histocompatibility and Immunogenetics; NHS Blood and Transplant; the Care Quality Commission; commissioning groups and tissue banks.

We received useful information and considerations from stakeholders. Over the next few weeks, we will be continuing to work with the DH and the transplant community to refine and confirm the proposals in advance of full implementation of the Organ Donation Directive by 27 August and will update you as soon as we have more news.

HTA and NHSBT workshop on serious adverse event and reaction reporting under the EU Organ Donation Directive

In our October E-newsletter we told you about an EU Organ Donation Directive (EUODD) serious adverse event and reaction reporting workshop for clinicians, which we held in conjunction with NHS Blood and Transplant. In addition to the presentations which we published at the time, you can now also read our report of the event.

There has been a delay in publishing the report while we have been working hard on other areas of the EUODD work, consultation and engaging with the community. You can keep up with our efforts on our website.

HTA response to the Welsh White Paper on an opt-out system for organ donation

The Welsh Government's consultation on their plans to introduce an opt-out system for organ and tissue donation ended on the 31 January. The White Paper outlined proposals to introduce legislation which would mean that if a person who had both lived and died in Wales had not indicated that they did not wish to be an organ or tissue donor, then it would be presumed that they did wish to donate and their family would be informed of this. The HTA response can be found on our website. As the organisation which currently regulates consent for organ and tissue donation in England, Wales and Northern Ireland, the HTA will be continuing to work with the Welsh Government over coming months.

Inspection pilot project launched

As part of our work to strengthen our regulatory processes and reduce the burden of regulation on those we license, we are piloting a new 'themed' inspection model with a small number of establishments in the Human Application sector.

The inspection will be undertaken by one Regulation Manager and will focus on recurring themes which have arisen across the sector. These themes will be compliance with HTA standards relating to quality management, contingency planning and risk management. The Regulation Manager will be able to look at these standards in greater detail and will be able to offer more detailed advice and guidance than if they were inspecting across all standards. At the end of the pilot, we will be gathering feedback from participants to evaluate its success with a view to applying the model more widely across the sector and into other sectors.

We have identified a small number of establishments to help us with this pilot based on the nature of the activity they undertake, the inspection schedule and the findings of previous inspections. Our staff will explain the nature of the pilot and the format of the inspection when they contact the establishment to arrange the site visit. The first pilot inspection will be in April and the pilot will run for three months.

Public engagement and the HTA

The HTA undertook a project, towards the end of last year, to gain some insight into the levels of confidence in the consent processes that allow for the ethical use of tissues and organs, and the regulatory system that governs them on behalf of members of the public.

The discussions covered a number of topics across the sectors we regulate, and included: views on giving consent for themselves; views on giving consent on behalf of others; reasons for confidence; and any hesitancy or negative reactions around giving consent.

While the project does not give us a definitive view of what the general public thinks, it has provided us with useful information about some of their interests and concerns, which we can feed into different elements of our work.

The project embodies a key objective of our communications strategy, which aims to focus on communicating with the public as well as continuing to communicate with our professional stakeholders.

You can read more about the project and the high-level findings in the Authority paper on our website.

Tissue for research

The HTA is continuing to look at how we can work with the transplant sector to address the issue of removal of tissue for research.

We are aware that there are some difficulties in this area at present for the transplant community, as a result of the requirements of the Human Tissue Act. We are restricted in what we can do, as the difficulties result from the legislation. However, we have been considering a number of licensing options and issued a position statement in November to extend existing post mortem licences that include removal. We are working with NHS Blood and Transplant to make this process clear to all centres, and are looking into introducing a new licence for removal of tissue for a scheduled purpose.

We have also been discussing other options with the Department of Health and while it has been confirmed that the legislation cannot be changed through the new EU Organ Donation Directive, there is a possibility of developing separate regulations to address this issue. While this might prove difficult, the HTA will be helping the Department to draft a proposal.

Licence fees 2012/13

The HTA will be issuing fee invoices to establishments in the tissue and cells for patient treatment (human application) sector in April and all other sectors in September.

Due to efficiencies we have made, licence fees reduce again this year. The fees are set out in this table: licence fees for 2012/13.

The HTA has not spent all of the fees collected in 2011/12 and expects to credit unused fees back to establishments. We will provide further details by the end of March.

Rise in confidence in the HTA for the post mortem sector

The HTA has published the results of our 2011 survey of the post mortem sector. The findings from the research are positive and show that there have been improvements in our relationship with the post mortem sector, and an increase in confidence in our work. Confidence in the HTA as a regulator has increased from 27% having a 'great deal of confidence' in 2010, to 40% in 2011. The findings also suggest that the sector has noted and appreciated the work the HTA has done with them over the last 12 months. However, we not complacent about the results and we are continuing to improve our relationship with the sector.

One of the HTA's key performance indicators in the HTA's business plan 2011–12 was to conduct a survey of the post mortem sector to see if levels of confidence in the HTA had changed in the period following the Ipsos MORI evaluation in 2010. A significant amount of work has taken place since then to improve the relationship between the HTA and the sector and to increase confidence in our work. Thanks to all stakeholders in the sector who participated in the survey. We will reflect on comments made as we develop our business plan for 2012/13. See section on the post mortem sector below for more information that addresses some of the feedback received.

Authority meeting, 24 January

The HTA held an Authority meeting on 24 January in London. Issues discussed included plans to implement the EU Organ Donation Directive, our post mortem sector survey report, our public outreach project and our response to the Welsh Government's consultation on the introduction of on an opt-out system for organ donation *in Wales. You can* download the meeting papers *from our website which also include updates on the arm's-length bodies' review and the Health and Social Care Bill.*

Licensing and inspections update

Since the HTA began licensing in 2006, through to the end of the 2010/11 business year, we completed 743 desk-based assessments and 615 site-visit inspections across our five licensed sectors. For the post mortem sector this means that we have now met our objective of inspecting all post mortem sector establishments within a three-year period.

To date in 2011/12 there have been 20 desk-based assessments completed – 11 tissue and cells for treatment, and nine research. This business year we have completed 159 site-visit inspections (82 tissue and cells for patient treatment, 54 post mortem, 18 research, four anatomy and one public display). Inspection feedback relating to quarters one, two and three of 2011/12 shows that 99% of respondents rated the overall inspection process as 'good' or 'excellent' and 94% said it has helped improve the way they work.

You can read our latest summary report of performance against HTA standards for all sectors on our website.

Inspections are usually scheduled according to assessed risk; however they may also be scheduled randomly or on a reactive basis following receipt of information. We continue to receive positive feedback about our inspections and we are keen to hear more of your views.

Further information about our inspection process including inspection reports can be found on our website.

Information for the anatomy sector

Position statement on the acceptance of donor consent for anatomical examination

The HTA has published a new position statement on the acceptance of donor consent for anatomical examination on our website.

Medical school staff are sometimes faced with the challenge of deciding whether the consent given by potential donors, often written many years before their death, is valid if it contains colloquial terminology and not the specific terms stated in the Human Tissue Act 2004 (the HT Act). "*Anatomical examination*" is not a term commonly used by the general public, and therefore may not be used in body donation consent documents, such as in personal letters or wills. The new position statement provides guidance on the circumstances under which the consent may be deemed acceptable and can be acted upon.

We hope that this new guidance, in addition to the advice we have provided to will writers, will reduce the number of body donations that are declined.

Information for the tissue and cells for patient treatment sector

Annual activity data 2011 update

Thanks to all the establishments that provided their annual activity data relating to human tissue for patient treatment in 2011.

We are currently analysing the information submitted and will be making a portion of the information available, in an anonymised format, via the EUROCET website. In addition to this, we will make some of the high level data available at events and in publications including the summary report of performance against HTA standards for all sectors.

Our inspectors review this information before inspections and it will be used as a tool for updating our licence management systems. To find out more about annual activity data requirements, please visit our website.

Please contact the HTA at enquiries@hta.gov.uk if you have any questions.

Authorising processes

In April, the HTA will start implementing European Commission requirements to authorise processes used to prepare tissues and/or cells for patient treatment. We will be asking establishments licensed for processing under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to complete a Preparation Process Dossier (PPD) four to eight weeks before the next scheduled inspection. The PPD will help establishments confirm the suitability of reagents and consumables, and demonstrate how quality is assured through validation and controlled with testing. Also, from April we will require new or improved processes to be authorised using the same procedure.

The PPD procedure will provide assurance that processes used to prepare tissues and/or cells are suitable for patient treatment. Establishments will also have confidence that their processes have been authorised. More information about PPDs will be available on our website from April. If you have any questions, please contact the HTA and ask to talk to a member of the Regulation team.

Information for the post mortem sector

Advice on locum Anatomical Pathology Technologists

Establishments in the post mortem sector occasionally need to employ locum Anatomical Pathology Technologists (APTs). To maintain standards, all Designated Individuals in the sector are reminded to check qualifications and references, before taking on locum APTs, or ensure that locum agencies have effective systems of checking in place. Furthermore, APTs should receive induction training and we strongly advise that they are subjected to a competency assessment before they are permitted to work in the mortuary or participate in post-mortem examinations.

Histopathology working group update

The next meeting of the HTA's Histopathology Working Group (HWG) is on 28 March. The agenda has yet to be confirmed, but topics so far include a paper which considers the HTA's regulatory approach to microscope slides and discusses the possibility of introducing a new, less burdensome approach, and a discussion on how to reduce the number of wrong body releases, which are coming to light through our serious incident notification system. We hope that the group will help us develop guidance that will be of use to all those working in mortuaries, as well as others, such as funeral directors and hospital porters, who may be involved in body release.

Protocols for police referrals

Earlier this year the HTA signed a protocol with the Association of Chief Police Officers and the National Policing Improvement Agency, which ensures the continuation of forensic pathology services in the event of regulatory action we take that results in licence suspension. The protocol is on our website. We are committed to ensuring that enforcement action takes place only when absolutely necessary and in full consideration of its impact, weighed against the risk of not taking action. The protocol represents a shared responsibility for ensuring service continuity and is a good example of collaboration with key stakeholders to ensure a proportionate approach to regulation. The approach set out in the protocol is mirrored in an HTA policy on the provision of coroners' post-mortem examinations in the event of regulatory action.

Publication of the Hull Royal Infirmary inspection report

In our December e-newsletter, we reported that the Chief Executive of Hull Royal Infirmary had invited the HTA to inspect the establishment to provide assurance to the Trust's Board about mortuary procedures and practices, following a serious incident involving a body that had been in long-term freezer storage. We have now published the inspection report on our website. The report contains information about the very effective steps that have been taken at Hull Royal Infirmary, which will be of interest to any establishment providing post mortem services.

Cremation and depressurisation of a Fixion nail from a deceased person

The HTA recently received an enquiry about the depressurisation of a Fixion nail from a deceased person to enable cremation. Crematoria usually require depressurisation before cremation as heating the pressurised saline solution poses a risk of explosion. All Designated Individuals in the post mortem sector are advised that removal or adjustment of a medical device, such as a Fixion nail or an artificial pacemaker, before a body is cremated are not subject to the consent or licensing requirements of the Human Tissue Act. Furthermore, because the activity is not licensable by the HTA, it need not take place on HTA-licensed premises.

Information for the organ and bone marrow transplant sector

Organ donations from living people

Between 1 April 2011 and 3 February 2012, the HTA approved 917 reports from Independent Assessors.

Between 1 April 2011 and 3 February 2012, the HTA referred 98 reports to a panel of HTA Members for decision because they involved altruistic, paired or pooled cases.

You can read more about organ donation on our website.

Bone marrow donations from children and adults who lack capacity to consent

Between 1 April 2011 and 3 February 2012, the HTA approved 55 reports from Accredited Assessors.

You can read more about bone marrow donation on our website.

Information for the Research sector

Shaping the Health Research Authority's future

A multi-agency project team has been established to shape the role the Health Research Authority (HRA) will play nationally. Dr Shaun Griffin, Director of Communications and Public Affairs at the HTA, is working part time as a member of that team. Looking at clinical and health services research conducted in the NHS, the team is carrying out a process review of the entire research project, from initial idea, development, funding, approval, conduct, compliance / inspection, to publication and translation. Going beyond the individual research project, the review will extend to an analysis of other projects involving the same researcher or sponsor.

By reviewing current systems and improvement programmes, understanding roles, and developing a common language, the team will identify areas for further improvement that will provide a unified approval process and promote proportionate standards for compliance and inspection.

It is currently gathering evidence and would welcome your contribution. More information, including a presentation on the HRA's work, is available on the HRA website.

Recent media stories about human tissue

December

The Express.co.uk highlighted the HTA in a story about altruistic donation.

January

The HTA was mentioned in a letter about altruistic donation published in BMJ. The HTA was referenced in a story about tissue retention in The Sun. We published a statement in response to this story. This story was also covered on The Mirror, The Daily Mail, PA, The Daily Telegraph, MSN, Rutland and Stamford Mercury, Police Professional, The Bournemouth Echo and on the Daily Echo website. We also published a statement on new plans for increasing living kidney transplantation.

February

The HTA was mentioned in a transplant feature in The Times. The HTA was also cited in a story about ovarian re-implantation in The Plymouth Herald, The Daily Telegraph, The Daily Mail and The Independent (Ireland). ITV Anglia broadcast a story about transplant and mentioned the HTA.

E-newsletter options

Our bi-monthly e-newsletter is available in HTML and plain text. If you have any trouble reading the plain text version, please log in and select ‘HTML’ as your preferred format. Previous copies of the HTA's e-newsletter are available in the news and events section of our website. Please feel free to forward this onto colleagues and encourage them to subscribe.

Readers can log in to personally mange their subscription and amend contact details. Should you need to unsubscribe, please log in and select 'no' to receiving email updates. If you have any problems unsubscribing please email: enquiries@hta.gov.uk.

Don’t forget you can ‘like’ the HTA by visiting our Facebook page. We also have a Twitter page so please follow us. If you have any comments please contact social.media@hta.gov.uk.