

Human Tissue Authority
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Dear Colleague

Post mortem sector update

Following the significant regulatory action taken by the HTA in relation to University Hospital Wales, Cardiff, late last year and the operational difficulties this caused in the area, I undertook to communicate changes in our procedures resulting from the lessons learned and to update you on other issues relevant to your sector.

The experience reinforced work we had underway to review our decision-making processes and lessons were learnt by all those involved. This letter gives details of some specific pieces of work that we are taking forward and their status.

New Histopathology Working Group

In collaboration with the Royal College of Pathologists (RCPATH), we have developed new terms of reference for our Post Mortem Sector Working Group, which has become the HTA Histopathology Working Group. The objectives of the group are to:

- maintain strategic oversight of the sector
- provide a forum for debate on sector-specific issues and inform implementation of resulting work streams
- report back to the Authority on key issues as necessary.

The Group will meet twice a year, following meetings of RCPATH's Specialty Advisory Committee on Histopathology, and agenda items will include topics proposed by the Committee, which it would like the HTA to consider. The first meeting of the HTA Histopathology Working Group will take place on 19 January 2011 and will be attended by Members of RCPATH, representing the various pathology specialisations, and other

stakeholder groups. The draft agenda for the forthcoming meeting includes an overview of new and improved HTA processes, including protocols established with the Association of Chief Police Officers of England Wales and Northern Ireland (ACPO) and the Crown Prosecution Service (CPS), and an update on the audit of retained material that the HTA required establishments to undertake earlier this year (see below).

Protocol to ensure the provision of forensic pathology services in the event of regulatory action taken by the HTA in England and Wales

The events at Cardiff identified the need for improved coordination and discussion between the HTA and others before a mortuary is closed. They also uncovered the lack of contingency arrangements in the area. We strongly advise establishments to have such arrangements in place to safeguard their provision of services.

To provide additional assurance, a protocol has been drafted by the National Policing Improvement Agency (NPIA) on behalf of (ACPO), the Home Office Pathology Delivery Board and the HTA, which will ensure arrangements are in place for the continuation of forensic pathology services in the event of a mortuary being temporarily closed for post mortem examinations. The protocol aims to ensure that there are contingency arrangements in place and that all parties work together to minimise disruption to services and inconvenience and distress caused to the relatives of the deceased. In particular, it states who the HTA should contact prior to taking any significant regulatory action, so that the parties involved can undertake an impact assessment, which will inform the decision and actions we take and ensure that they are proportionate and risk-based. The draft protocol is currently with the above three organisations awaiting sign-off.

Protocol for managing potential criminal breaches of human tissue legislation

Most police referrals are likely to result in service interruptions and with this in mind, we have drafted an additional protocol that sets out the basis for referral to the police in cases of alleged criminal breaches. We have an in principle agreement that this protocol will be signed by ACPO, ACPO (Scotland), the CPS, the HTA and the NPIA. It clarifies the responsibilities of all parties in the event of a police referral and will ensure that there is effective communication between parties and that the action taken by the HTA and the police is proportionate. The document will be signed off in early 2011.

Update on audit of retained post mortem tissue

As you know, licensed establishments were required to complete an audit of retained post mortem tissue by the end of September. The decision to instigate the audit across the sector was informed by evidence gathered during inspections that gave rise to concerns about unnecessary tissue retention. The objective of the audit was to understand more fully

the nature and quantity of relevant material stored on licensed premises and the reasons for its retention so that the HTA can provide appropriate advice.

The HTA consulted with RCPATH to define the specification of the audit, to help ensure that it was proportionate whilst giving the HTA the necessary assurances of observing the consent requirements of the Human Tissue Act.

The HTA acknowledges that the audit has been difficult for some organisations to undertake. However, feedback from many Designated Individuals on inspection has been that it was a useful exercise, which has resulted in significant improvements in practice, a tightening up of procedures and increased confidence that material is only kept with appropriate consent.

All establishments have now submitted the information, for which we are grateful. The information is being reviewed to determine the extent to which:

- there is retention of tissue without appropriate consent
- systems to dispose of tissue in a timely manner need improvement
- establishments are experiencing communication challenges with coroners or police forces

We will provide advice and guidance to individual establishments, where required. We will also issue a report of the findings of the audit, along with an update on how establishments are meeting our standards and an analysis of serious untoward incidents, by 31 March 2011. Where the audit shows common difficulties across the sector, for example in relation to the traceability of microscope slides, these findings will inform HTA regulatory policy to ensure that we take a proportionate, risk-based and fair approach, and we will ensure that the sector is involved through the Histopathology Working Group.

Listening to your views

An independent evaluation of professional opinion conducted on our behalf by Ipsos MORI shows that nearly nine in ten (86%) professional stakeholders have a “great deal/fair amount” of confidence in the HTA as a regulator. However opinions in the post mortem sector were less positive with 20% having “not very much/no” confidence (against 9% overall). That said, 76% of respondents in the post mortem sector were confident in the HTA and we are working to build on this confidence and plan to seek your views again over the next year.

The post mortem sector raised some issues with us regarding communications with coroners, we will continue to provide advice and guidance to help support individual establishments to address these matters.

Initial feedback from our compliance reports have shown that our regulation of post-mortem examinations has helped mortuaries improve the standard of service and care they provide, so the public can have confidence that the dignity of deceased people is maintained and they are treated with respect. Tissue can only be kept for research or other specific purposes when consent has been obtained from the family, so people can be confident their wishes will be respected. I hope that we can continue to work together to achieve this aim to ensure that public confidence is maintained as our functions transfer to new organisations as a result of the Arm's Length Bodies review.

I hope this gives you a clear overview of the work we are doing to take forward the lessons learnt and other activities we are undertaking to support public and professional confidence.

I would be grateful if you would communicate this on to your colleagues. We will also continue to provide updates on progress in our e-newsletter and through other channels.

Yours sincerely,

A handwritten signature in cursive script, appearing to read 'Diana Warwick'.

Diana Warwick
Chair