

## Minutes of the HTA Histopathology Working Group

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**Date** 5 May 2017  
**Venue** The Grosvenor Hotel, 101 Buckingham Palace Road SW1W 0SJ  
**Protective Marking** OFFICIAL

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### Present

#### Members

##### HTA

Ms Sarah Bedwell, Director of Regulation (SB)  
 Ms Caroline Browne, Head of Regulation and Chair of HWG (CB)  
 Dr Lorna Williamson, HTA Member (LW)  
 Mr William Horne, HTA Member (WH)

##### Royal College of Pathologists

Dr Michael Ashworth (MA)  
 Dr Michael Osborn (MO)

##### Coroners Society of England and Wales

Dr Fiona Wilcox (FW) (by teleconference)

##### Home Office

Mr Jeff Adams (JA)  
 Martin Allix (MA) (by teleconference)

##### Association of Anatomical Pathology Technology

Mr John Pitchers (JP)

##### IBMS

Mr Andrew Usher (AU)

#### In attendance

Ms Fiona Maleady-Crowe, Regulation Manager and Secretary of HWG (FMC)  
 Ms Jess Porter, Head of Regulation (Observer, JP)  
 Ms Lisa Carter, Regulation Manager (Observer, LC)

## **Item 1 – Welcome and introductions**

1. CB welcomed Jessica Porter, Head of Regulation for the Organ Donation and Transplantation sector, and Lisa Carter, a Regulation Manager, both of whom attended to observe the meeting.
2. Apologies were noted from The Right Reverend Graham Usher, Andrew Hall, Anne Thorpe, Dean Jones, Derek Winter and Guy Ruddy.

## **Item 2 – Review of minutes of last meeting (28 October 2016) and matters arising**

3. Members had the opportunity to comment on the accuracy of the October 2016 meeting minutes prior to their publication on the HTA website. No further amendments were requested.
4. Actions from the October 2016 meeting were reviewed.
5. Update on ACTION 2 from April 2016 meeting: *CB to provide LW with RCS contact to discuss the inclusion of a paragraph about the RCS specimen collections project in a future edition of the RCPATH bulletin; action is ongoing. LW received an out of office from RCS contact.*
6. Update on ACTION 1: Action complete
7. Update on ACTION 2: *CBr to produce advice for Designated Individuals about the removal of samples for DNA testing; action outstanding.*
8. Update on ACTION 3: Agenda item for discussion
9. Update on ACTION 4: Agenda item in RCPATH update
10. Update on ACTION 5: Ongoing
11. Update on ACTION 6: Action complete
12. Update on ACTION 7: Action complete

### Item 3 – HTA update

13. HTA updates were provided as follows:

- i. **Compliance update.** Every two years the HTA undertake a compliance update exercise across all sectors, with the exception of the Human Application sector. The compliance updates aim to provide information on how establishments are demonstrating compliance between HTA site visit inspections. Last year we asked establishments to assess their capacity to deal with the winter pressures, and to identify pinch points. The HTA are mindful of the work involved in completing the updates, and of the implementation of the new Codes and Standards. As such, the compliance updates will be designed to enable the HTA to identify emerging and current risks but be lighter touch this year.
- ii. **Triennial review.** Although completed 18 months ago, the Department of Health have recently published the HTA's triennial. SB provided a brief summary of the major outcomes of the review, including the HTA continuing to exist and a recommendation of the McCracken review to update the Human Tissue Act 2004 (HT Act). The previous government had stated that the HT Act will not be reviewed during their term.

#### **ACTION 1: CB to send triennial review to HWG members**

- iii. **On the horizon.**  
Taphonomy – the HTA continue to liaise with the establishment wishing to set this up. The establishment is in the process of getting approval from the university and securing funding. The HTA and the Home Office have met to discuss the implications of taphonomy. The HTA is looking at the options available and will liaise with stakeholders as any proposals develop.

Consent for this activity is not covered by the HT Act, this is one of the issues to be considered and may require an amendment to the HT Act. MO highlighted that RCPATH would like to be involved in the work surrounding this project.

#### **ACTION 2: CB to circulate paper to the Group once it has been drafted.**

Cryopreservation – A paper was presented to the HTA Authority recently which generated interesting discussion. The HTA CEO has

written to DH with key issues arising from the Authority discussion. Professor Barry Fuller from UCL Medical School presented information on how cryopreservation is currently being used to members of the Authority and HTA staff. The presentation will be useful when drafting guidance documentation around cryopreservation. The HTA is considering producing guidance that will be made available to the public and to establishments. The guidance could provide information about the types of questions that should be asked of those providing the cryopreservation as well as identifying any relevant HTA standards which could be followed voluntarily.

File on 4 – BBC4 Radio have made a documentary about pathology in the United Kingdom, which focuses on the shortage of pathologists. The Royal College of Pathologists and AAPT have also been approached and provided input. AAPT provided the BBC with details of mortuaries in the country who may be able to contact families who have been affected by the shortage. Following the winter capacity and contingency update performed by the HTA in 2016, a number of areas were identified where the shortage of pathologists is affecting the release of bodies from mortuaries.

MO highlighted a study performed by Cancer Research UK on the availability of pathologists to perform routine diagnosis as well as post mortem (PM) examination. The study highlighted a decrease in the number of young pathologists available which will have an impact on cancer diagnosis.

FW provided details of a piece of work being carried out by the Coroner's society relating to the shortage of pathologists, and the impact this is having not only on mortuaries, but also on families. In addition, the quality of the post mortem examination deteriorates over time.

**ACTION 3: FW to share findings from this work when available.**

Cremation Regulations – The Ministry of Justice has published its infant cremation consultation response in July of this year. On 1 October a new statutory definition of ashes came into effect. The aim is to make sure that everything in a cremator following a cremation is considered as ashes and dealt with in accordance with bereaved parents' wishes. MoJ has set up a National Cremation Working Group, made up of representatives from the cremation and funeral industries, voluntary organisations who support bereaved parents, medical professionals and other government departments with an interest in cremation and includes the HTA. The group is providing

expert input into MoJ's work to further improve cremation legislation and practice. Its first priority is amending statutory application forms regarding options for disposal of ashes, and bringing the cremation of fetuses of less than 24 weeks' gestation into the remit of the cremation regulations.

#### **Item 4 – RCPATH update**

##### 14. MO provided an update from RCPATH

- i. **UKAS.** UKAS approached RCPATH to discuss the possibility of undertaking accreditation of mortuaries, including the post mortem examination. A meeting between RCPATH, UKAS and the HTA took place to discuss the potential for this. MO discussed the extensive examination procedure in place for pathologists to gain their qualifications. It is not considered appropriate for UKAS to undertake accreditation of this process. UKAS did not appear to be aware of how few consented PM examinations are undertaken in the United Kingdom on a yearly basis and have concluded that this might not be an appropriate area for their consideration. The matter will be discussed internally with colleagues at UKAS. Joint inspections between the HTA and UKAS have provided conflicting reviews and SB highlighted that the decision to accredit the mortuary with UKAS lies entirely with the Trust, it is not mandatory. It was felt that establishments are often not clear that this is the case.

#### **ACTION 4: MO to release a statement from RCPATH detailing the requirements for accreditation.**

AAPT distributed a feedback form to members regarding UKAS inspections, and any issues arising. The feedback has been compiled and sent to UKAS for review. In parallel to the feedback form, AAPT and UKAS have been discussing involving an APT as a key member of the inspections.

#### **ACTION 5: JP to share results of the survey with the Group**

- ii. **Death investigation group.** The Royal College of Pathologists regularly receives a large number of requests for information regarding post-mortem examinations. As such, a Group has been formed consisting of members of RCPATH, the HTA, the Coroner's Society, and AAPT. The purpose of the Group is to provide guidance for professionals. The Group will produce guidance for professionals regarding UKAS in an aim to reduce the burden of the College.

- iii. **Cross sectional imaging check.** Guidelines are being produced by two groups regarding cross sectional imaging in PM examination and the guidance will be provided to RCPATH and the Royal College of Radiologists for input. The draft guidelines are expected in early 2018.
  
- iv. **Implanted Medical Devices.** CB and MO were contacted by the Medicines and Healthcare products Regulatory Agency (MHRA) regarding the removal and investigation of implanted medical devices following death and PM examination. RCPATH have previously been approached by the Coroner's Society and produced guidance, which the MHRA appeared to be unaware of. The guidance sets out that if an individual has an implantable device and if the pathologist is of the opinion that it contributed to the cause of death, then the Coroner should be approached to give authority for the implantable device to be investigated.  
The MHRA have requested that all implantable devices are sent for investigation. Currently, where pacemakers are sent for investigation, they are grouped together and sent in batches, which means that the interrogation of the device will focus on the functionality of the device, and not whether it contributed to the death of the individual. RCPATH has highlighted that it is impractical to send every device for interrogation, particularly as the results of the investigation will not provide an independent assessment to the Coroner. In addition, there is a large volume of individuals in the United Kingdom with pacemakers, and other implantable devices, meaning that it would be difficult to investigate these with all associated documentation. The MHRA have requested some amendments to the RCPATH guidance and this will be discussed further with the Death Investigation Group.
  
- v. **Radioactive seeds.** RCPATH have identified an individual to write guidance on the appropriate removal of radioactive seeds, however further information has suggested that the actions required for radioactive seeds depends entirely on the nature of the seeds. Advice has been provided that the team providing the treatment to the deceased should be contacted to provide further information on the nature of the seeds.

## Item 5 – HWG survey results

- 15. A survey was distributed to HWG members in March regarding the efficacy of the Group. CB thanked the Group for their input. The results indicated that

members felt that the Group functions well, meets the objectives set and is useful for horizon scanning and in informing the Authority of how the HTA develop regulatory policy in the PM sector.

16. Members were asked in the survey whether they felt a lay member would be useful and the Group were in agreement that this would not be necessary as there is lay representation from the Authority members.
17. The Group were also asked whether they felt there should be more representation from the Home Office and there were mixed views on this. MO suggested raising it as an AOB in the next Death Investigation Group meeting.
18. Members were asked if they felt a formalised agreement for their participation in the Group would be useful. This will be in the form of a letter and will include the terms of reference. Colleagues in the HTA are analysing the functionality of all Groups in the HTA.
19. CB is considering what documents that go to the Authority on a quarterly basis should be distributed to HWG Members.

**ACTION 6: CB to distribute a summary of the survey to the Group.**

**ACTION 7: CB to distribute papers in advance of next meeting and the Group will comment on whether they felt this was useful.**

### **Item 6 – Mortuary Staffing**

20. HTA staff are regularly asked on inspection and through enquiries whether we can provide advice on the number of staff that should be working in a mortuary to accommodate the PM examination and other work, and there is a growing expectation that specific guidance will be produced. CB asked the Group whether they feel it is practicable to provide guidance.
21. JP highlighted the difficulty in providing guidance. There are many factors to consider, not just the number of PM examinations being performed. There are regional variations in the work load mortuaries; some mortuaries do not have an on call, some mortuaries restrict viewings while others do all viewings requested. JP carried out a benchmarking exercise and noted a significant variation in the workload and staffing of mortuaries in the core cities. The Group was in agreement that it would be difficult to provide guidance.

22. JP suggested the HTA being involved or providing guidance around qualification of APTs. It is in the standards that mortuary staff must be suitably qualified, however due to funding a number of mortuaries are hiring mortuary assistants, or staff from the laboratory to perform duties (other than PM examination-related activities) in the mortuary. APPT have concerns around this practice, and are working with the Royal Society of Public Health to see if the qualifications can be delivered in a modular way.

#### **ACTION 8: AAPT to write to HTA highlighting concerns**

#### **Item 7 – AOB**

23. MO asked whether there has been an update regarding medical examiners. FW provided an update that this has been delayed until late 2019 however this will be reviewed again. There may be additional information following the election in June 2018.
24. LW highlighted bulletins issued by RCPATH, and that members of the Group may be contacted to contribute as the theme of the next bulletin is 'Death and Dying'.
25. CB thanked members for their attendance and contributions. The next HWG meeting will take place in October 2017. FMC will circulate potential dates to members in due course.