The Royal College of Pathologists
Pathology: the science behind the cure

Briefing on tissue samples becoming part of medical records of deceased adults

26 January 2022

Introduction

Most post-mortem examinations that take place are carried out at the request of a Coroner and are performed without the consent of the next of kin. According to the Coroner's statistics for England and Wales in 2020 there were 79,400 post-mortem examinations ordered by Coroners in 2020. Of these,17,002 (21%) included histology, and 19,802 (25%) included toxicology. Once the Coroner's work is complete, these tissue samples (in the form of small blocks and slides) must be destroyed unless specific consent is provided by someone in a qualifying relationship. Given the way the system works, this consent is logistically very difficult to obtain in practice and therefore very little tissue taken during Coroner's post-mortem examinations is kept. The RCPath has been concerned for some time about the lack of tissue available from post-mortem examinations in England, Wales and Northern Ireland for teaching, audit, and research purposes.

This issue was the raised by a number of organisations, including RCPath and the British Medical Association, as part of the McCracken Review of the Human Tissue Act which recommended in 2013 that:

> *'Consideration should be given (inter alia) to: reducing the scope so that microscope slide and tissue block samples and bodily products such as saliva, urine, and faeces are excluded'*

The Government accepted this recommendation but this issue has not subsequently been progressed.

The Importance of Retention

The interpretation of the findings from a post mortem is often subjective, rather than definitive. Causes of death are often a result of the exclusion of other causes, and the examination should be regarded as a snap-shot of the deceased at the exact point of death, rather than necessarily a documentation of the events that led up to the death.

This means that pathologists are highly reliant on the supply of accurate and comprehensive clinical information relating to the circumstances leading up to and around the time of death to be able to provide a reasonable clinico-pathological correlation and cause of death. This especially relates to point 1 below, but also to examples 2 and 3 – pathologists often find out aspects of the deceased's life and / or treatment after completing the examination but before authorising the report.

Examples where the retention of human tissues could be beneficial:

1. **Providing information about or confirming the cause of death**

   In occasional cases pathologists have to go back to the tissue blocks where circumstances come to light, months or years after an investigation is completed. This can throw a different light on information received at the time of the post-mortem, and may lead to a different interpretation of changes previously reported or lead to additional, or new, investigation methods to determine precise pathological changes. Occasional forensic deaths can be masked by natural disease processes and storage of tissues and fluids, as part of the medical record, helps to clarify these issues at a later date when the new information is brought to light.

   The use of genomics is a fast developing area which means the possibility of usefully going back to tissue to further clarify or refine a cause of death, be that for the coroner, the family, research or teaching, has become more likely.

   However, the cause of death, once given by the coroner, will almost certainly not change. Therefore, in practice, genomic studies on stored historic post-mortem tissue are likely to be for the purpose of finding out useful information for families, for research or teaching. It is particularly important for families to know genetic risk. This is becoming more common and will continue to do so. If the tissue is destroyed this option is not available.

2. **Research**

   Going back to tissue blocks months or years after death investigation is complete can be useful to assess the impact and causation of inherited diseases, many of which are being better understood and categorised in light of new information relating to underlying pathophysiological mechanisms and patterns of inheritance. Storage disorders, which are mostly genetically inherited, like Fabry or Gaucher's diseases are good recent examples of conditions where the retention of tissues after autopsy has enabled pathologists to provide new information furthering our understanding of these diseases.

   At post-mortem, it is possible to take larger amounts of tissue which allows an appreciation of overall tissue architecture and the geographical variation of pathological changes seen within an organ affected by disease; much more so than in biopsies which, when taken from the living, tend to be very thin tissue cores. This is especially relevant when the changes affect the heart (e.g., in Fabry disease) or brain where taking anything more than very tiny amounts of tissue from a biopsy in life is impossible.

   Post-mortem tissue, by its nature, is often samples of severe end stage disease such as cancer which has led to death and may have escaped therapy. Biopsy/resection tissue from the lining is unlikely to be the same as it is likely earlier stage and often predates, or has not escaped, treatment so will give different information.

3. **Education**

   The ability to use stored tissue blocks and slides, in the context of full clinical history and autopsy findings, provides invaluable teaching material for trainee and qualified pathologists in the field of autopsy pathology.

Current legal framework

The Coroner's (Investigations) Regulations 2013 ('the Coroner's Regulations') provide that Coroners should notify families of the fact that samples of material will be taken at the post-mortem and advise them of the options for dealing with the material after the inquest has taken place. One of the options under the Coroner's Regulations therefore is retention of the material for medical research or other purposes in accordance with the Human Tissue Act 2004. However, whilst families are required to choose what should happen to any tissue blocks and slides taken, there is currently no mechanism for providing them with information about this option, which means that, in practice, most histology slides and blocks of tissue are disposed of and are lost for teaching, audit and research purposes.

Proposal to amend the legislation

RCPath supports the position regarding blocks and slides in the Human Tissue Act 2004 to be reviewed and to be brought in line with the position in Scotland where tissue samples, in the form of blocks and slides, automatically become part of the person's medical record following a post-mortem examination. The Human Tissue (Scotland) Act 2006 distinguishes between these samples and whole organs (which, by contrast, do not automatically become part of the medical record), reflecting the emotional significance these body parts have. In Scotland, authorisation is required for the retention of any *organs* following a post-mortem examination but not blocks and slides.

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About the Royal College of Pathologists

The Royal College of Pathologists is a professional membership organisation with more than 11,000 fellows, affiliates and trainees, of which 23% are based outside of the UK. We are committed to setting and maintaining professional standards and promoting excellence in the teaching and practice of pathology, for the benefit of patients.

Our members include medically and veterinary qualified pathologists and clinical scientists in 17 different specialties, including cellular pathology, haematology, clinical biochemistry, medical microbiology and veterinary pathology.

The College works with pathologists at every stage of their career. We set curricula, organise training and run exams, publish clinical guidelines and best practice recommendations and provide continuing professional development. We engage a wide range of stakeholders to improve awareness and understanding of pathology and the vital role it plays in everybody's healthcare. Working with members, we run programmes to inspire the next generation to study science and join the profession.