THE FOUNDATION FOR SCIENCE AND TECHNOLOGY

DINNER/DISCUSSION SUMMARY

"Pathological Specimens and Data – What controls should be in place?"

Held at the Royal Society, 6 Carlton House Terrace, London SW1Y 5AG
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Sponsored by
Cancer Research UK
Department of Health
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In the Chair: The Rt Hon the Lord Jenkin of Roding
Chairman, The Foundation for Science and Technology

Speakers: Dr Robert Coleman
Chief Scientific Officer, Pharmagene Laboratories
Mr Steve Catling
Chief Executive, The Retained Organs Commission
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Warden, Barts Hospital and The London School of Medicine and Dentistry

The debate took place against the background of the consultation document issued by the Retained Organs Commission in February on a possible regulatory framework for unclaimed and unidentifiable organs and tissue removed at post mortem examinations.

It was noted in discussion that there were different sensitivities in relation to different kinds of tissue. The main concerns, and the remit of the Commission, primarily concerned organs and tissue retained following post mortem examination, and this was the main subject of the consultation document[1]. There was little evidence of pressure to return surplus tissue retained following surgery. It was possible that people might have views about the disposal of some parts of their bodies following an operation, and the example was cited of a Mexican emperor who lost a leg but gave it a royal funeral. In general, though, it was thought that most patients would be relaxed about tissue surgically removed from them.

Pathological specimens constituted data, and it was for consideration how far consent ought to be needed for the use of patient data, including photographs, for research. One participant saw a fundamental difference between data about patients and bits of people, but thought that pictures could nevertheless be sensitive. Another response was that issues over the use of information about patients for research ought to be referred to local ethics committees. The General Medical Council was said to have declared it unethical to give data to cancer registries without consent, but partial information would be useless.

A participant from the commercial sector saw anonymity as the key to using personal data. Using anonymised information caused no problems so long as the researchers could find out about the clinical context and go to an intermediary to get further information where necessary. Another speaker, however, was not sure that anonymity would solve all the problems when studies needed linked data about patients. Appropriate arrangements could be made for the future, but the use of existing information in medical records raised more difficult issues. It was suggested also that anonymisation was being applied without thought following Alder Hey. Thus one local ethics committee had insisted on consent or anonymity for a study of spontaneous abortion, even though the

[1] www.nhs.uk/retainedorgans/consultationfeb02.pdf (note particularly the summary which sets out the purpose of the consultation)

samples in question had been given expressly for that purpose.

Consent raised issues of both practicality and principle. For surplus surgical tissues it was suggested that, while explicit consent was ideal, implied consent for non-contentious research uses could reasonably be assumed. An alternative view was that existing surplus tissues should be seen as abandoned. It would be foolish to prompt people to repossess their removed colons.

For the future one possibility might be to get consent for research use of the tissue which was to be removed at same time as consent was given for the operation itself. Another practice which one speaker had encountered in another country was for a patient being admitted to hospital to be given a menu of possible events, from surgery to autopsy, and be asked to sign up to all the possibilities. The same might be done at an even earlier stage, in the GP's surgery. A further option might be to require patients positively to opt out of allowing their surplus tissues to be used for research, just as in a teaching hospital medical students were given access unless the patient expressed a wish to the contrary.

Whatever means were adopted for obtaining consent, the messages delivered needed to be simple and comprehensible to people under great stress. People also needed to be treated with consideration and not talked down to. One speaker had had the experience of giving tissue in a London hospital and reported that the exercise was a great success technically but a disaster from the point of view of courtesy.

One speaker suggested that these problems might be side-stepped, on the ground that there would be general support for the retention of surplus tissues without consent. In one study of perinatal deaths where the cause of death was not clear most of the parents wanted tissues retained even without consent, partly in recognition of the possible need for evidence to exonerate the parents of responsibility for the deaths. It was observed, however, that people who said they agreed with the retention of particular classes of tissues in particular circumstances without consent were in effect giving their own consent. They could not speak for those who disagreed. Another participant thought that a balance should be struck between the rights of the individual and the benefit of society, but leaning toward the latter. Against this it was argued that there was no need to address a conflict between individuals and society if the large majority of people did not object to the use of tissues for research.

The question was raised whether people might have reservations about the possible use of retained tissue for commercial research. One response was that would be quite mistaken, because the private sector produced good science and all research had a commercial element somewhere. Against this it was suggested that people with unusual conditions might not want to give their tissues away, because they might be able to make money out of them.

Another cause of unease over the research use of autopsy specimens, it was suggested, might be a lack of understanding over how much of the body would remain to be buried or cremated. It might help if a broad indication could be given of how much tissue was needed for research. Unfortunately that would be difficult. The requirement was for well-classified collections of specimens for particular conditions, and that could not readily be translated into a need to take a certain amount of a particular body. It was certainly necessary however, to communicate with the public on the purposes and benefits of organ donation, and it was suggested that many potential donors would want to know in detail what would happen at autopsy.

There was general concern over the demonisation of doctors following the Alder Hey and Bristol scandals. Some perinatal pathologists had been harrassed into leaving the profession, and autopsies were not happening as a result. Pathologists needed to explain to the general public what they did. It had not, for instance, been made plain in discussions of Alder Hey that it was the clinical team or the clerk who sought consent, not the pathologist. Other medical disciplines ought to help convey the importance of pathology: the paediatricians had been active in this.

It was important to persuade the media to engage in a more constructive debate and recognise the essential part played by the existing archives of surgical tissue. Some diseases would never be seen again: for Hodgkin's disease, for example, reference was still made to the original specimens. One of the strengths of British cancer research was the studies which had been made of different tissue types over many years, and these would be incomplete if patients could not be tracked to the final outcome. Many were now dead, and it would not be feasible to go back to all the relatives for permission to use the archived material.

In a concluding comment one participant suggested that the issues were in essence not very complicated. The keys to progress were consent, where it was possible; education and information, so that consent was informed; and not underrating the intelligence of the public.

Jeff Gill