The Human Tissue Act

Reassurance for relatives, at a price

On 1 September 2006 the full provisions of the Human Tissue Act 2004 came into force. This represents the conclusion of the UK government's response to concerns about inappropriate retention of organs after postmortem examination, especially paediatric specimens. It introduces criminal sanctions to enforce valid consent and the proper handling of the deceased and their tissues, supported by a licensing system, overseen by the newly created Human Tissue Authority.

But the act does more than this. As part of a European Union directive, sections implemented in April 2006 enforced a licensing system for transplantable tissues. Public display of human tissues, such as the "Body Worlds" exhibition of Gunther von Hagens, will require written proof of consent before death and a Human Tissue Authority licence. An offence that can loosely be called "DNA theft" is also created, and restrictions are placed on the use and storage of tissues from the living. The act's definition of human tissue is broad; consequently, it is possible to commit a criminal act by undertaking research using urine or faeces.

The controls on tissue from the living caused particular concern to the Royal College of Pathologists and to researchers. They were not demanded by any public outcry. This part of the act does not apply to Scotland. When the Scottish parliament later developed the Human Tissue (Scotland) Act 2006, sections on tissue from the living were not included.

Ministers initially suggested that consent for research should be obtained from every NHS patient, for every sample taken. Researchers saw the impracticality and feared that the sort of research that formed the basis of our current classification of cancer would suddenly become illegal, just as the genomic revolution provides new tools to re-evaluate the NHS archives of tissue samples from living patients. If they could be used legally and ethically, those archives would be the biggest and best documented "research tissue bank" in the world.

The government insisted that consent is "the golden thread" running through the legislation, but the NHS has maintained the view that recording the wishes of every patient is impractical. This is despite evidence that patients would prefer to be asked just once, with the answer to cover all future samples.[1] Lord Warner, on behalf of the government, said that recording and retrieving consent for every sample would produce "a considerable bureaucratic problem."[2] So there has been a gradual accommodation. The chief medical officer initially asserted that consent would be needed to use tissue from the living in audit or teaching,[3] but this was withdrawn before the act was passed. Research using anonymised samples from the living without consent will remain lawful if an ethics committee approves. Requirements for licences for storing tissue from the living have been reduced by recent ministerial regulations.[4] The Human Tissue Authority has tried hard to ensure that, within the letter of the law, any activity that is for the benefit of patients should not be inhibited.

Inevitably some uncertainty exists about the new licensing system, and it is legitimate to wonder whether the considerable effort and expense incurred is justified. Problems remain, but aside from the bureaucracy, the act should reassure the public and provide a secure legal framework for professionals who use human tissue. Paradoxically, if this proves not to be the case, it may be the fault of health service staff rather than the legislators. The legislation is complex, and the risk of criminal sanctions causes fear among professionals. This induces a tendency to "gold plate" the legislation; the response becomes "if in doubt, don't do it." I am repeatedly told by colleagues that the act prohibits things that in fact it doesn't, or demands things that it doesn't, or that a licence is required when it isn't. Patients will suffer if this phase does not pass soon.

Research ethics committees are at the forefront of this, because they now have a statutory duty to decide not just whether research without consent is ethical, but whether or not it is lawful. They would do well to consider the 2005 Nobel Prize for Medicine, awarded for the discovery of *Helicobacter pylori* as the main cause of peptic ulcers.[5] This work started by staining sections from 100 archival gastric biopsies—highly speculative research, without consent, external funding, or peer review.

The risk to those 100 patients was zero. The benefits are now obvious; the discovery of *H pylori* has saved the lives of thousands and reduced the suffering of countless more. Would this research be possible today? Would our new system for tissue regulation still pass this *Helicobacter* test? The letter of the law passes the test, but the system may still fail as a result of researchers being deterred by fear or bureaucracy, or by ethics committees demanding unobtainable consent.

Sadly we will never know if the next *H pylori* discovery is blocked. Research that does not occur remains invisible, and nobody will know what we have lost.

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