Regulation of human tissue in the UK

The Human Tissue Act 2004 became law in England, Wales, and Northern Ireland in the aftermath of an organ retention scandal. 12 years on, what has been achieved? Ann McGauran reports.

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For the **Human Tissue Act 2004** see http://www.legislation.gov.uk/ukpga/2004/30/contents

For the ***Organs for Transplants* report** see http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf

The Bristol Royal Infirmary inquiry was set up in 1998 to investigate the deaths of babies who underwent heart surgery at the hospital in the late 1980s and early 1990s. It also uncovered the practice of keeping children's hearts and other organs without the informed consent of parents. Revelations emerged of similar retention of organs at the Alder Hey Children's Hospital in Liverpool. These led to a further inquiry and a report in 2001 showing that 2080 organs had been removed from 800 children.

A wider review led to the Human Tissue Act and the setting up of the Human Tissue Authority (HTA) as a regulator. The HTA's regulatory remit includes organisations that remove, store, and use human tissue for medical treatment, research, education and training, post-mortem examination, and display in public. It also gives approval for bone marrow and organ donation from living people. The key principle underpinning the Act is of consent as fundamental to the lawful removal, storage, and use of body parts, tissues, and organs. The Act lists the purposes for which consent is required. Removing, storing, or using human tissue for scheduled purposes without appropriate consent is an offence under the Act. It also created a new offence of DNA "theft".

A conference on June 23 organised by the Royal Society of Medicine provided an overview of the Act's effect on areas, including organ donation. It was called "one of the most important pieces of legislation in medicine" by consultant nephrologist and medical ethics expert Antonia Cronin. Other speakers generally thought the Act had brought about positive change. Some also highlighted several regulatory challenges. These included a lack of standardisation affecting inspection, increases in health-care providers' costs, and the administrative burden. A longer-term concern is how the legal, regulatory, and ethic frameworks governing human tissue and data and information could be reconciled.

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One family's perspective

David and Hazel Thewlis's baby son Paul died suddenly in 1983 and underwent a post mortem at Alder Hey Children's Hospital. In 1999, the couple became aware of the organ retention issue. They found out their son's heart had been retained without their consent. Mr Thewlis said the Act was "one of the finest pieces of legislation enacted". He added: "It's respected globally by other countries as the gold standard."

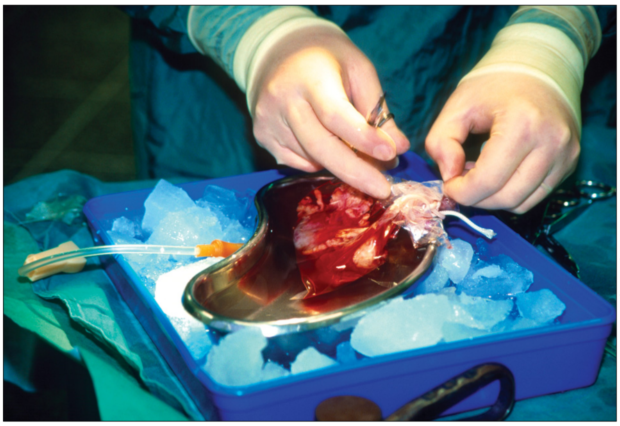
He said the debate surrounding organ retention did change a culture. He added: "The law gave us confidence that there were clearly defined boundaries set out in the Act and the HTA enforced and regulated these with consistency."

A new system came into law in Wales on Dec 1, 2015, of deemed consent for organ donation. The British Medical Association has now called for an opt-out system similar to the Welsh one to be implemented in England, Scotland, and Northern Ireland. Should it be implemented in the other UK countries? Mr Thewlis does not think so. He said: "I don't think there's any need or value in England going the same way. Presumed consent is a fundamental change both morally and ethically. Facts globally confirm that an increase in donation comes from a proper and adequate infrastructure and public awareness rather than presumed consent."

Health professionals' view

How does Cronin believe the Act has influenced organ donation and transplantation? In her view, the "whole spirit" of the Act's decision to place a high premium on informed consent was subsequently fully captured in an independent report from 2008 from the independent Organ Donation Taskforce set up by the UK Government. The report concluded that any movement away from a system based on expressed consent must be shown to be a justifiable exception to the current norms.

So did the focus on the guiding principle of informed consent in the Act cause a subsequent increase in donation rates? Cronin thinks so. At the time the 2004 Act came into being, the disparity between the number of people waiting on the transplant list and the number of donors coming forward was increasing, said Cronin. The taskforce, she said, had been established by the government in 2006 to suggest solutions that would



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deliver an increase in transplants. In 2008, the taskforce said in its report *Organs for Transplants* that a 50% increase in organ donation after death was achievable in the UK within 5 years. Did this happen? Cronin said: "Yes, this list [of people waiting for transplants] came down. It shows the importance of not only a legal framework but [also that] implementing policy and clinical practice in response to that framework actually really matters."

However, it was the expansion of donation after circulatory death (DCD) programmes not an improvement in family consent rates that led to the increase in the number of donors since 2008, according to a report in 2013 from NHS Blood and Transplant.

Cronin made a clear link between the 2004 Act's decision to empower the regulator to develop a Code of Practice for the definition of death for the purposes of that Act only and the legitimacy gained by DCD programmes. The Academy of Medical Royal Colleges (AoMRC) moved ahead of the regulator and published a revised Code of Practice in 2008 for the diagnosis and confirmation of death. The HTA then published a draft position statement in 2012 saying it did not see a need for a further, separate code.

The revised AoMRC code had, Cronin said, meant that "it's possible to define death from neurological criteria and it's also equally possible to define it by cardiopulmonary criteria". Clinicians could then "confirm to ourselves that we have two forums for deceased donation—either donation after brainstem death (DBD) or donation following circulatory death (DCD)".

Cronin said the consensus on DCD was "it's legitimate—it's become legitimate through the Act, through the taskforce, and it's become legitimate through the AoMRC Code of Practice".

Mike Watts is director of the Wolfson Cellular Therapy Unit at University College London Hospital. He believes external regulation of transplantation centres can help in many ways with safe practice, including reduction of risk through ensuring quality governance systems and providing a network through which to report problems and solutions.

However, he said there were challenging aspects to it, including time and cost. Inspection could also be "non-risk based"—disproportionate to the level of risk involved—and hampered by a lack of standardisation in transplantation procedures between transplantation centres.

> **"'...please support and hold with the greatest respect the benefits and assurances the Human Tissue Act 2004 has provided for mankind.'"**

He highlighted concerns that arose at Great Ormond Street Hospital in London in 2013 about a number of patients with cancer whose bone marrow transplants did not work because of problems with the stem-cell freezing process.

He said: "The implications for the Act, or any external regulator, is that the processes you undertake in a clinical application setting have to be well standardised, defined, and validated and risks identified in order for the regulators to inspect on that basis."

John du Parcq is a consultant in cellular pathology at South West London Pathology, an NHS partnership to provide a single pathology service for southwest London and beyond. In his view the HTA "has done a fantastic job in laying the spectre of the organ retention scandal". For tissue governance, providers had moved to a much tighter system, where "you have to know where your tissue is, what it's doing, and what you plan to do with it".

But he highlighted a number of concerns, including gaps in the HTA's remit such as mortuaries that do not do autopsies. He also said there was a "huge administrative burden" from regulation that has affected the way that mortuaries operate, and "some evidence that some hospitals have decided this is too much for them".

Triumphs and challenges

Hugh Whittall is director of the Nuffield Council on Bioethics. Prior to that position, he was branch head at the Department of Health from 2002 and was closely involved with the preparation and passage of the Act. In his view, the Act led to the confidence of those families seriously affected beforehand that "what had gone before" was not going to happen again. It also resulted in "the confidence of professionals that somebody was not going to tap them on the shoulder a few years later and say they should not have been doing that".

He views the long-term challenge as the issue of tissue banking. The value of a tissue sample, he says, is beginning to reside more "in the huge amount of data it can deliver once you put it through any kind of biochemical or genetic analysis".

"So to some extent, tissue banks could become redundant once you have got the data or information in the tissue. We then move from the framework of human tissue regulation into the framework of data and information regulation." The interaction of regulatory control and legal and ethical frameworks is going to be very difficult, he thinks, because "the two areas have not necessarily matched up completely".

The current legislation, he believes, should be capable of working for "another 10 or 15 years, because we quite deliberately introduced a degree of flexibility and discretion that could be exercised by the HTA".

For Mr Thewlis, who lost his baby son 32 years ago, this is good news. His views on the Act are clear: "My final message would be to please support and hold with the greatest respect the benefits and assurances the Human Tissue Act 2004 has provided for mankind."

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