The Royal College of Surgeons of England

Series Editors: **Robert Wheeler**
Colin Johnson

Ann R Coll Surg Engl 2010; **92**: 189–192
doi 10.1308/003588410X12628812458897

Legal reviews

This is another paper in a series of reviews dealing with legal aspects of surgical practice. We have asked several distinguished authors, expert in their field, to contribute to this series. Our aim is to provide up-to-date guidance for surgeons in potentially difficult areas of their practice and academic work, whilst at the same time re-affirming the legal boundaries within which they work.

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Legal implications of tissue

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ABSTRACT

This paper reviews the legal rules that govern the way surgeons deal with human tissues during the course of diagnosing and treating their patients. The topic is dominated by the *Human Tissue Act 2004*, which was enacted in September 2006; thus, the article applies specifically only to England, Wales and Northern Ireland, since Scotland has separate legislation (*Human Tissue (Scotland) Act 2006*). Although the *Human Tissue Act 2004* was built largely upon a plethora of legal principles that were developed throughout the Commonwealth and in the US, some of the principles underlying it will be equally familiar and applicable to surgeons across the world. Much everyday clinical activity falls outside the remit of the Act, and depends both upon other statutes, and on common law rules, principally those relating to consent.

KEYWORDS

Human Tissue Act 2004 – Clinical activity – Consent

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The 'ownership' of human tissue is an interesting aspect of English law. It is neatly illustrated by the common law doctrine that there is 'no property' in a body; thus, there is no legal owner of a dead human body or, by inference, of 'dead' body parts. Despite this, some cases provide support for regarding materials that regenerate, such as blood, urine and hair, as 'property'.[1]

The modification of a body, including the measures taken to preserve, dissect and prepare a body part for teaching or display, do confer a property value upon it, but this value, which is capable of being owned, is derived entirely from the skill and ingenuity that these processes required. When a junior technician at The Royal College of Surgeons of England removed body parts for the use of an artist who wanted to use them for making sculptural moulds, there was a charge of theft.[2] The work done on the body parts, transforming them into specimens, conferred a value upon them, and they were, therefore, capable of being stolen.

Instead of conferring property value, the law has focused on the definitions of 'legal possession' of the body, which is

a concept describing a transient 'guardianship', in contrast to ownership. A person, such as an employee of a hospital trust, may have legitimate 'possession' of a body or body part until such time as a person with a greater claim (for example, a relative) arrives to take possession of the body for burial or appropriate disposal. Alternatively, a practitioner might be viewed by the law as having legal possession of a tissue if that tissue had been 'abandoned' or removed with consent, by a person, for example in a surgical operation.

Although the origins of this common law are now centuries old, it had resulted in the fact that in the UK, since body parts are not 'owned', the laws that provide citizens with a remedy for damage, theft, or inheritance disputes cannot be invoked in the way that might otherwise be applied to something one has ownership of. This, in turn, goes some way to explain the development of the widespread practice, since Victorian times, of the collection and storage of 'abandoned', 'waste' or 'worthless' bits of human bodies for education, display or possible scientific research, without transgression of the common law or latterly, human tissue legislation. This view of excised tissue was echoed by the Nuffield Council's report in 1995, recommending that, where tissue was removed during a procedure for which a patient had given their consent, the tissue should be regarded as abandoned by the person from whom it had been removed.[5] However, the Council's premise that citizens saw no value in their abandoned body parts began to look outdated, particularly in the context of the evolving biotechnology industry, and its requirement for discarded human tissue. This was illustrated by the disquiet caused following the disclosure that thymus glands excised during paediatric cardiac surgery were being sold to pharmaceutical companies, albeit with the parents' consent for the tissue to be retained for research.[4]

Courts have examined the issue of who can legitimately profit from the commercial exploitation of a tissue sample.[5] Following the elective removal of a spleen from a man with hairy cell leukaemia, an immortal cell line was created from it, leading to a patent application, commercial development and considerable financial benefit. When he discovered the existence and origin of the cell line, the patient took court action for, amongst other things, the loss of his property rights.

The court, perhaps predictably, found no property in body parts, and rejected this element of his claim. It cited the risk of destroying the economic incentive to biomedical research in support of this rejection. Ironically, the pharmaceutical interest thus created was defended on the basis of a species of property law, patent. However, the court upheld the patient's complaint that his tissues had been used without his consent.

A seismic shift in public and then political attitudes occurred after the revelation that several English hospitals had retained patients' body parts without the consent of their families, and most particularly, of their parents. The fact that the existing law made no provision to proscribe such behaviour, which was considered to be profoundly unethical by those who investigated the facts, describing the views of the hospitals involved as 'institutional paternalism';[6] ramifications of the situation led to a public and political outcry. The Chief Medical Officer responded with advice,[7] followed by a government consultation,[8] which was to form the basis of the *Human Tissue Act 2004*. The new law provided an opportunity radically to reform the existing legal framework, and its enactment caused the old law to be repealed, including the *Human Tissue Act 1961*, *Anatomy Act 1984*, *Corneal Tissue Act 1986*, and *Human Organ Transplants Act 1989*.

Human Tissue Act 2004 (HTA 2004)

Some clinical activities outside the immediate realm of diagnosis and treatment are affected by this Act. The important thing to understand about this rather impenetrable piece of legislation is that it impinges very little on the everyday diagnosis, investigation and treatment of surgical disease. These activities are governed by the rules that govern obtaining a patient's consent, as provided by the common law and the *Mental Capacity Act 2005*, very helpfully laid out as guidance by amongst others, the General Medical Council.[9]

The HTA 2004 is applicable only to scheduled activities listed in Table 1. Crucially, it will be seen that there is no mention of diagnosis or investigation or treatment. Thus, considering the blood tests performed as a diagnostic or pre-operative exercise, or the tissue taken at biopsy, or during excisional surgery, none of these appear on the schedule and they are, therefore, excluded from the remit of the Act. However, when considering any clinical activities, it must be recognised that legal rules may be derived from many sources, the identity of which may not be apparent. If the content of the Department of Health consent form is considered, some sections will be necessitated by common law, some by the *Mental Capacity Act 2005* and still more by the HTA 2004.

Included in the HTA 2004 is the storage and use of relevant material from a living person and the removal, storage and use of relevant material from a dead person for 'scheduled purposes' with 'appropriate consent'.

Relevant material is defined as 'material, other than gametes, which consists of or includes human cells'.[10] Hair and nails from a living person, and embryos outside the human body, are excluded by the Act.

Scheduled purposes are defined as those purposes that generally require consent under the Act, whilst material used for other purposes is excluded from the remit of the

Table 1 Schedule 1 activities

Part 1: Purposes requiring consent: general

1. Anatomical examination (*macroscopic examination by dissection for teaching, studying or researching into the gross structure of the body*)
2. Determining the cause of death
3. Establishing after a person's death the efficacy of any drug or other treatment
4. Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)
5. Public display
6. Research in connection with disorders or the functioning of the human body
7. Transplantation

Part 2: Purposes requiring consent: deceased persons

8. Clinical audit
9. Health-related education or training
10. Performance assessment
11. Public health monitoring
12. Quality assurance

Authors' italicised text.

Act. Thus, as Table 1 indicates, using a tissue sample for health-related education or training, clinical audit, or quality assurance does not invoke the Act if the sample is taken from a living person. Readers whose hospitals use the Department of Health consent forms will recognise the requirements for patients to consent for their tissues to be examined for diagnostic purposes, teaching, audit and research, and may thus question why these responses should be sought, if the HTA 2004 excludes these purposes in the living patient? This is necessary to conform with the regulations that govern the necessity for consent in general; however, it would also be essential evidence of consent for the scheduled purposes should the patient subsequently die, since specimens separated from a dead patient will be 'caught' by the Act, whereas tissue separated from a living patient is not.

The HTA 2004 prescribes rules concerning the storage and use of relevant material in circumstances covered by purposes 1–12.

Consent during life (for activities described in the scheduled purposes) is provided by the patient in the normal way. Although the Act does not stipulate written consent in every case, it is required, wherever possible, for post-mortem activities, and is always required (together with the signature of a witness) for anatomical examination and specimens for public display. The Department of Health consent form commonly prompts the patient to consent or refuse for their tissue to be used for some of the purposes (*e.g.* audit, research, public health surveillance, quality control and education). Determining the cause of death is, understandably, not addressed.

The HTA makes an exception for purposes 8–12 for tissues taken from living patients, since the use of a patient's tissues for these purposes is considered intrinsic to the patient's care, and consistent with public policy;[11] consent is, therefore, not required (from the perspective of the HTA 2004) for living patients, but it is nevertheless included in the Department of Health form.

If the patient is not competent to provide consent, then the HTA 2004 directs the surgeon straight to the *Mental Capacity Act 2005* (MCA 2005), so the process of taking consent for the scheduled purposes is incorporated in, and effectively inseparable from, the consent for the procedure from which the tissue will be derived. The MCA 2005 prescribes the necessary formalities in recording consent.

If the patient has not provided their consent during life, after death, none of the activities listed 1–7 can be lawfully carried out on their tissue without appropriate consent being obtained. For activities 8-12 consent requirements depend on whether the tissue was acquired during life or after death. It is lawful to store and use tissue from the living for audit, quality control, education *etc.* without their consent and then use these tissues after death without permission. However, if the tissue is taken and stored after death then appropriate consent must be sought.

This appropriate consent is defined in terms of the person who provides it. It may have been provided by the patient before his or her death, or by a representative nominated by the patient. In the absence of consent from this source, a person with a qualifying relationship with the patient may be identified by the clinician. The HTA 2004 provides eight ranks of people with a qualifying relationship, with spouse or partner ranked first, parent or child second, brother or sister third, the intervening rankings dealing with common family linkages, and 'friend of longstanding' last.

The practical application of this is that, if educational, audit or research activity involves tissue taken from a patient after death, consent to store and use the tissue is required, but that the consent can be sought in a methodical way. There is ample anecdotal evidence of the frustration of surgeons who have been unable to get access to dead people's tissue when trying to pursue such work, and find themselves blocked by an authoritative, yet nebulous, refusal from departments of pathology. Doubtless, these departments have been diligent in ensuring that the rights

of deceased patients and their families should be respected but, since the advent of the HTA 2004, neither clinicians nor trusts who are holding the specimens need to be concerned that they are doing the wrong thing in releasing relevant material tissue for scheduled purposes, providing appropriate consent is in place.

Tissue used for diagnosis

Importantly, under the HTA 2004, scheduled purposes exclude the use of relevant material for diagnosis and treatment, so these activities are not governed by the Act and remain covered by common law. However, the Act does cover the use of one person's material to make a diagnosis where it is primarily for the benefit of another person. Using one person's material for the benefit of another (usually to allow more accurate risk prediction or diagnosis in a relative) has been relatively rare to date, but is likely to become more common as 'genetic medicine' expands. For example, performing immunohistochemistry on a colonic tumour would not invoke the Act if it were to make a primary diagnosis in that person. However, if the test were mainly to benefit a relative (who might want appropriate screening or a predictive genetic test) after the death of the index patient, the Act would be engaged. However, because the HTA 2004 governs only samples that include human cells, extracted DNA (which is acellular) is exempt, so a diagnosis from DNA in one person for the benefit of a relative does not have to conform to the Act.

These apparent contradictions could, in the absence of consent, lead to the irony of the prevention of a cheap and easy test, such as immunohistochemistry, whilst the complex and expensive DNA sequencing is exempt.

Tissue used for audit and quality assurance

As scheduled purposes, these require consent for tissue derived from dead people, although as far as the act is concerned, not for tissue separated from the living. However, since all the terms are defined loosely and overlap, it can be very difficult to distinguish between audit, quality assurance and research. Different decision matrices have been designed to enable those devising projects to determine how the activity is categorised. In general terms, if doubt exists, it is prudent to obtain appropriate consent; if the project is research, consent is mandatory.

When the law was enacted, there was great concern that researchers might be deterred by the new bureaucracy, and the point was made that research that is not performed 'remains invisible, and nobody will know what we have lost'.[12]

Tissue used for transplantation

This topic will be covered later in the series.

Conclusions

The *Human Tissue Act 2004* has greatly simplified the complex legal framework that preceded it. When read in conjunction with the General Medical Council's guidance on obtaining consent, it provides a clear mechanism for surgeons' lawfully obtaining tissue from living and dead patients, and covers most circumstances that would be necessitated by clinical, academic and research activities. The Act does not impinge on the diagnosis and treatment of disease, which is primarily covered by the more general surgical consent with which we are already familiar. It remains to be seen whether the disadvantages foreseen by the research community eventuate.

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