Who owns my body – thee or me? The human tissue story continues

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ABSTRACT – The recent furore regarding the retention of human organs and tissue has resulted in a public outcry about medical practice in this area. Public inquiries have exposed a tradition of practice within the medical profession that was not concordant with contemporary ethical and legal standards. The legal framework governing this area, particularly the Human Tissue Act 1961, is now acknowledged to be inadequate and out of date. Following wide consultation, the Government has proposed new legislation to include a stricter regulatory framework, a statutory body for overseeing and licensing the retention and use of human organs and tissue, and the creation of new statutory offences with sanctions for their breach. Fundamental to this legislation will be the requirement for adequate and appropriate consent. Specific issues such as the status of tissue blocks and slides, surplus surgical tissue, and the potential implications for research and transplantation are considered. An awareness of these developments is of relevance to all practising doctors.

KEY WORDS: consent, human organ, human tissue, law, medical ethics

The ongoing furore regarding the retention of human tissue and organs has led to unprecedented criticism of the medical profession.[1] Since 1970, approximately 54,000 organs, body parts and stillborn fetuses have been retained from post-mortem,[2] and 21,000 adult brains have been kept after coroners' examinations alone.[3] Historically, a patchwork of practice has existed that has not been concordant with contemporary ethical and legal standards. This is not least because the Human Tissue Act 1961 (which governs the removal and retention of human tissue) is inadequate and out of date. Extensive consultation has been undertaken on a range of issues relating to medical practice in this area.[4–7] The resultant Government proposals[8] have led to a draft Bill[9] and reform is now imminent.

This article explores the legal issues around human organ and tissue retention and transplantation, against the backdrop of current law, the emerging consensus opinion and the interim framework proposed by the Department of Health (DH).[6] It is likely that reform in this area will have a major impact on future medical practice, so an awareness of these matters is relevant to all medical practitioners.

The existing legislative framework

Removal of tissue from the deceased for therapeutic, research and educational purposes is governed by the Human Tissue Act 1961 ('the 1961 Act'). A person who is lawfully in possession of the corpse is permitted to authorise the removal and use of parts of the body (for any or all of these purposes) provided that the deceased requested this, or that after making such reasonable enquiry as may be practicable, there is no reason to believe that either the deceased or any surviving spouse or relative objected to such removal or use. Such authority extends to managers of hospitals or other institutions where the corpse may be lying. The 1961 Act has generated considerable controversy regarding the breadth of the term 'relative', and the ambiguity surrounding who might be the 'person lawfully in possession of the body' and what amounts to 'such reasonable enquiry as may be practicable'. Furthermore, there are no sanctions included in the statute for its breach.[1] The 1961 Act also provides authority for hospital post-mortem examinations.

The Coroner's Act 1988 provides the statutory authority for a coroner to hold an inquest to ascertain the cause of death. There is no requirement to

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Key Points

- **Recent controversy surrounding human organ and tissue retention has led to criticism of the medical profession**
- **Existing legal controls governing this area are inappropriate for modern society**
- **Following wide consultation new legislation is now imminent**
- **Proposed legislation will create a stricter regulatory framework, an overarching regulatory body and new criminal offences with sanctions for breach**
- **The retention and use of tissue blocks and slides, surplus surgical tissue, research and transplantation pose specific challenges that need to be addressed**

obtain consent prior to ordering a forensic post-mortem, which may be conducted despite objections from relatives. In practice, the autopsy is usually performed by a hospital pathologist who acts as agent of the coroner. The coroner's powers cease in relation to the deceased once the inquest is concluded and therefore as a matter of law the coroner's authority (as well as that of the pathologist) terminates with regard to further dealings with the body. Although the Coroner's Rules 1984 (Rule 9) authorise the continued retention of tissue for such periods as the coroner sees fit, this is only for the purposes of ascertaining the cause of death. Regulation of the retention of tissue from the deceased beyond the purpose allowed by Rule 9 is still controlled by the 1961 Act. Furthermore, a recent report[10] recommends no fundamental change from this position and consent should be sought for any retention of tissue unconnected with the justification of a coroner's autopsy.

Transplantation of organs

The Human Organ Transplants Act 1989 ('the Act') contains additional statutory provisions relating to the transplantation of organs. The Act prohibits commerce in relation to organs for transplantation procured from either living or deceased persons. It is an offence to remove an organ from a living person with the intention to transplant, or to transplant such an organ, unless there is a genetic relationship between the donor and the donee, as defined within the Act. In the absence of such a relationship, the transplant is regulated by the Unrelated Live Transplants Regulatory Authority (ULTRA), which may approve any specific transplant subject to the satisfaction of certain safeguard conditions.[11] The Act defines 'organ' as 'any part of the human body consisting of a structured arrangement of tissues which if wholly removed cannot be replicated by the body', and thus principally applies to non-regenerative body parts.

Exercising control

The legal concept of rights of 'ownership' permits trading. If applied to persons, this would commodify the body and undermine the Kantian notion of the dignity of human beings. In law, therefore, 'not only does no-one else own my body, neither do I'.[12]

Although legally there is 'no property in a corpse',[13] proprietorship rights may be obtained through the 'application of work and skill' to the body or its parts, based on the Lockean notion of the acquisition of property through the investment of labour.[14] English jurisdiction has accepted this principle, and applied it even in recent cases. In *Kelly*,[15] a conviction for theft of body parts from the Royal College of Surgeons was affirmed on the basis that dissection and preservation procedures constituted the 'application of work and skill', resulting in a change of those parts from their natural state, thereby conferring proprietorship rights upon the College. The Government wishes to retain this 'exception' in its recent proposals.[8] Pathologists routinely 'fix' tissue and make slides, but in the case of *Dobson*[16] preservation techniques alone were held to be insufficient for the exception to apply. Where the work of pathologists is sufficient to activate this exception there is a tension with the responses to the consultation document, *Human bodies, human choices*, which considered that pathologists should not be entitled to retain material following post-mortem unless specific consent has been given.[4,17]

The absence of proprietary rights in a corpse could be viewed as undesirable inasmuch as it does not facilitate legitimate and beneficial medical objectives, such as cadaveric organ transplantation and teaching autopsies.[18,19] A more desirable option might be for the lawful acquisition of the body or its parts, by means of a detailed statutory framework that includes adequate controlling preconditions. Such a scheme would enable the permitted and beneficial uses of a cadaver and its parts, whilst protecting legitimate medical interests and providing statutory sanctions for breach, thereby removing existing inconsistencies in the law.

The right to control tissue from living individuals is equally problematic. A Nuffield Council of Bioethics working party[20] has favoured the stance that a living person 'abandons' human tissue removed for diagnostic or therapeutic reasons, a view mirrored in the California Supreme Court case of *Moore*.[21] A diseased spleen was removed for therapeutic purposes and later used to develop a cell line for commercial distribution without the patient's knowledge. The court held that whilst the patient should have been informed of such potential future use, he no longer retained any legal interest in the tissue which was considered abandoned. There is currently, however, no parallel decision to *Moore* within our own jurisdiction.

The view of the Nuffield Council, as in *Moore*, arguably promotes the supply of tissue for research. However, it is questionable whether the concept of abandonment is appropriate in the absence of a person's clear intention to relinquish all interests in such tissue. This issue is paramount considering the technological advances that can use DNA from surplus tissue to detect specific characteristics and for propagating cell lines for commercial purposes. The Health Council of the Netherlands has stated that, given the increasing number of ways in which tissue can be analysed and used, it is no longer possible to assume that patients will lay no claim to such surplus material.[22] It is suggested that the preferred legal position would be that the right to abandon such tissue vests in the person from whom it originates.

Consent

Lack of informed consent lies at the root of the controversy surrounding tissue retention and the Government has committed itself to reforming the law in this area.[8] Living patients must give valid consent, or register an objection, to tissue storage and use. Patients need to be provided with suitable information, be given the opportunity to ask questions and consent voluntarily.[8]

Currently the law is inadequate where the deceased has not expressed his or her wish regarding organ or tissue removal. The 1961 Act permits the retention and use of tissue in the absence of objection from a surviving spouse or relative and after making such 'reasonable enquiries' as are practicable. This legitimises action on the basis of 'implied consent', although arguably this

may follow *unsuccessful* attempts at contacting relatives. The Government, however, proposes to embed the need for explicit informed consent in legislation and has published a code of practice as well as model consent forms.[5]

Explicit and informed consent ought to be a legal requirement where the deceased was silent as to his or her wishes, although it is important to remember that relatives are often experiencing extreme grief and psychological stress at this time. However, whether relatives should be permitted to override a positive request by the deceased is questionable. Information needs to be imparted in a considerate and empathetic manner. Whilst professional bodies continue to advocate that the clinical consultant has the primary role in interacting with relatives at this time,[23] it must be remembered that unfamiliarity with post-mortem procedures could lead to discrepancies between what is discussed and what is actually done by the pathologist. It has been argued that the pathologist should have a much more interactive role with relatives at this stage.[23] An alternative approach would be for a team of staff, specially trained for this purpose, to engage in the process of obtaining consent. Whichever model is adopted, there is a clear need for better services for bereaved relatives, as well as greater skills for medical staff to deal with issues of information and consent in this context.[24,8,25]

Tissue blocks, slides and surgical waste

Clarification is required regarding the retention and use of minute quantities of human material in tissue blocks and slides. One view is that this should be treated no differently from organs and tissue, whereas the opposing view asserts that this should form part of the clinical record and represent property of the NHS.[7] The McLean Report in Scotland states that tissue blocks and slides raise issues quite distinct from those associated with organs,[25] and recommends that, unless there are specific objections, the authorisation for a post-mortem study should include the preparation of blocks and slides as an integral part of the examination. The Report advocates that where valid authorisation has been given, the hospital authority should act as custodian (as opposed to owner) for the retention and use of such tissues as part of the hospital record for legitimate medical research and educational purposes.[25] The McLean Report[25] and the Retained Organs Commission (ROC),[26] however, consider that tissue obtained previously without proper authorisation or informed consent should be returned to relatives at their request. The Government prefers the view that tissue blocks and slides would be subject to the same rules as tissue generally.[8]

The huge genetic potential for tissue engineering has sparked considerable debate as to whether future legislation should cover cellular components of tissue. The DH has stated that 'organ and tissue' should include anything that contains human nucleic acid.[6] Materials shed naturally such as hair or nail clippings might be excluded, except in relation to the proposed new offence of DNA theft (using human tissue for DNA testing without the consent of the individual).

A consensus is emerging in relation to tissue removed from living persons for diagnostic or therapeutic purposes.[6,8] Consent must be obtained both for its retention and use beyond clinical care. The DH views non-clinical use as distinct from that offering potential benefit to the patient. There is therefore a need for explicit consent, which in principle should be addressed separately. Non-clinical use could include quality assurance, clinical audit, education, training, public health monitoring and research. However, it considers that tissue left over after diagnosis or treatment could be used for in-service training and quality assurance without requiring specific consent as these represent aspects of overall patient care, provided that there is a mechanism in place for informing patients that such use may be made. As regards formal education, public health surveillance and further laboratory testing, patients should have the right to refuse by opting out if they so choose.

Research

Explicit permission should be sought for retention of organs and tissue for research from living patients.[6,8] Where such consent has been obtained, it is still uncertain whether it would be permissible to use such tissue for future different research projects. There is concern that complex consent procedures could severely curtail research.[27] The experience of the Peterborough Tissue Bank suggests that the public does not object to the use of waste tissue removed during therapeutic surgery even for commercial research,[28] although there is greater reluctance to consent to the use of post-mortem tissue.[29] It has been suggested that, for surplus tissue, implied consent on the basis of lack of any objection should suffice. A generic consent process might be appropriate, facilitated by a centralised NHS record for all patients.[30] This appears logical, although an option should be included for individuals to prospectively opt out of future research, such as projects relating to abortion, genetic testing and commercial applications that might be considered controversial.

Regarding archival tissue, the DH suggests that each potential future use should be considered on its merits.[6] If valid consent had previously been given, it needs to be considered whether this consent remains sufficient. When the donor is identifiable and the validity of previous consent is ambiguous or non-existent, then further consent would be necessary from the person concerned or, if deceased, authorisation would need to be obtained from the person closest to him or her. Archival tissue may be used for some forms of research without patient consent, though subject to approval of a research ethics committee if such consent is impractical to obtain, or if this would cause distress to those contacted.

Unidentifiable or unclaimed tissue from post-mortems should be subject to controlled access for research purposes.[6] Permitted categories for research would include those where consent has previously been clearly and properly obtained, where there is no possibility of tracing the tissue back to an individual or group, and where use is minimally invasive, such as observational research or where minute amounts of tissue are used,[9] subject to evaluation and approval by a research ethics committee.

Transplantation

Organ transplantation raises intricate ethical and legal issues and must be governed by an effective and appropriate regulatory framework.[31,32] In relation to the deceased, there is a conflation of the separate notions of 'consent' and 'lack of objection' in the 1961 Act. However, whilst the latter forms the substance of the Act, explicit consent is invariably sought from relatives, for the use of organs and tissue for transplantation from the outset. Whilst for most people, explicit fully informed consent from relatives may represent the gold standard, this tends to shift the balance subtly towards relatives and away from the wishes of the deceased. This runs counter to various other European jurisdictions and might be a factor in the reduced availability of organs for transplantation. Whilst relatives of the deceased adult should be permitted to make a decision to donate or to object to donation where this reflects the wishes of the deceased, or where these wishes are unknown, it is less clear why relatives should be able to veto a request to donate, or to donate contrary to the deceased's wishes. An exception exists in respect of young children, who lack the maturity to form their own views.

There is a substantial consensus that the dichotomy between related and unrelated living donors should be abolished, in favour of a single system for transplants from living persons regardless of the relationship between the donor and the recipient.[17] New legislation should legalise perfusion after death in order to preserve organ function whilst the views of the deceased, or those closest to them, are ascertained.[17] Transplants from living people (for example, living liver donation) should be regulated according to the degree of risk involved, and there should be a full public debate on risks and benefits before such treatment is routinely offered.[33]

Conclusion

The purpose of new legislation in this area would be to provide a consistent legal framework for issues surrounding the removal, storage and use of human organs and tissue. An acceptable balance needs to be attained between the rights and expectations of individuals and families and the wider public interest such as medical research, education, training and public health monitoring. New legislation will need to be drafted that is compatible with the Human Rights Act 1998 and takes into account other influential international developments such as the European Convention on Human Rights and Biomedicine (yet to be ratified in the UK).

Fundamental to any future legislation would be a detailed requirement of consent for the removal, storage and use of bodies and body parts. Such a framework should provide for the lawful acquisition and use of human tissue. The express informed consent of relatives will serve to align law with existing practice, and legitimise the removal, retention and use of organs and tissue for therapeutic and research purposes. In addition, statutory codes of practice need to be developed in relation to matters such as communication to families about post-mortem, the conduct of post-mortem examinations and the disposal of human tissue. Human organ transplantation should continue to operate under current arrangements and the proposed reforms are anticipated to outlaw all dealings in body parts giving rise to financial gain. It is envisaged that legislation would create a number of new offences, which would include taking or using human organs or tissue without consent, trafficking in human bodies or parts, carrying out activities outside those licensed by the Human Tissue Authority, and DNA theft. Criminal sanctions would be imposed for breach.

It is proposed that a new statutory body, the Human Tissue Authority (HTA), would have overarching responsibility concerning human tissue, its storage and uses, as well as transplantation. This would subsume ULTRA and incorporate the functions of HM Inspector of Anatomy (as set out in the Anatomy Act 1984). The HTA would have regulatory powers in relation to human tissue banking for therapeutic use, the storage of organs and tissue for research, training, quality control and audit, as well as the donation, storage and use of human bodies and the conduct of post-mortem examinations. It would have the power to impose licensing requirements on organisations responsible for undertaking these activities.

Human organ and tissue retention and use is an area fraught with complex legal and ethical issues. A paradigm shift is required in the legislative framework as well as in medical practice if the crises of recent years are never to be repeated. It is essential that doctors have an understanding of why problems have arisen and how future legislation in this area might affect their practice.

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