

new developments

The Use of Human Tissue: An Insider's View

D. Gareth Jones

Department of Anatomy and Structural Biology, University of Otago

Introduction

Late nineteenth and early twentieth century anatomy was characterized by the dissection of the unclaimed bodies of the poor and mentally ill (Richardson, 1988). Although these cadavers were obtained legally, the ethical nature of this practice is open to debate (Jones, 1994). Since the late 1950s in New Zealand, this practice has given way to the use of bequeathed bodies, in line with the Human Tissue Act 1964. With this Act informed consent was established as the central plank of the bequest procedure, which is strictly regulated by a regime based on Schools of Anatomy, Inspectors of Anatomy, and licensed anatomists.

In other words, for many years anatomy departments have been vastly different places from their early nineteenth century forebears in Europe and America, where grossly unethical practices were rampant. This unsavoury past forced the anatomical world to adopt regulated practices, with a well-substantiated ethical basis, even if anatomists in more recent years have thought less about ethical issues than they might have. In this, anatomy has stood in sharp contrast to pathology and medicine, where the demands for accountability have, until recently, been muted.

The Human Tissue Act 1964 also regulates post mortem examinations, although the strictures regarding these are less precise than for anatomical examinations (dissecting). It may be that the lack of an ethically disquieting past left pathology relatively unregulated, so that the practice of organ retention was accepted even in the absence of informed consent. The ramifications of such a questionable practice have now caught up with pathology in the form of the Green Lane Hospital saga in New Zealand, the Bristol and Alder Hey episodes in the United Kingdom (Bristol Royal Infirmary Inquiry, 2001; Royal

Liverpool Children's Inquiry, 2001), and the uproar surrounding the Institute of Forensic Medicine in Australia (Walker, 2001).

Unethical and Illegal Uses of Human Tissue

In 1995 in the United Kingdom the Nuffield Council on Bioethics published a report: 'Human Tissue: Ethical and Legal Issues'. The reason for this report is well expressed in the Introduction (p.1).

We are entering a new age of biotechnology and genetic engineering. Medical procedures that were pure science fiction a generation ago are a reality today. One aspect of the recent and rapid advances in biological and medical research is that human tissue is being used in an increasing variety of new ways. Many of these developments . . . have unquestionable benefits; but using human tissue in different ways also raises questions of law and presents new ethical dilemmas.

The broad vistas of the Nuffield report were soon to be replaced by far more focused reports precipitated by crises in medical practice. In the late 1990s in the United Kingdom, the debacle in Liverpool centring on Alder Hey Hospital shook confidence in the integrity of the medical profession. The vast collection of children's organs commenced in 1948, but was accentuated between 1988 and 1995 when practically all organs were retained for ostensibly research purposes. Unfortunately, practically nothing was done with these organs, in that both routine histology and research were neglected. The plethora of failings on the part of a particular pathologist, together with management failings, pointed to a serious lack of informed consent and concern for the welfare of next-of-kin (Royal Liverpool Children's Inquiry, 2001). The scandal at Alder Hey reached far beyond the mere retention of organs

without consent, allied as it was to other unethical practices.

The events at Green Lane Hospital in Auckland earlier this year brought out the same issues, although without the excesses of malpractice demonstrated in Alder Hey. The motive for organ retention had been research into congenital heart conditions, a motive that should not be maligned or lost sight of amid the legitimate concerns regarding lack of informed consent.

In Australia in March 2001 a television program made allegations of unlawful conduct against staff at the Institute of Forensic Medicine in Sydney. In the wake of these an Inquiry was set up by the state government (Walker, 2001). The allegations questioned whether provisions of the Coroners Act 1980, the Human Tissue Act 1983 and the Anatomy Act 1977 had been contravened. In particular, they concerned the removal at post mortem of long bones and joints from cadavers for research purposes, and the misuse of donated bodies by striking one on the cranium with a hammer, by scalding another, and by stabbing others. There had been no informed consent for any of these procedures. In the Inquiry's recommendations the wishes of the deceased emerged as paramount, as did the central role of clearly enunciated ethical standards for pathologists and other medical practitioners.

The impact of the events in the United Kingdom has led to an amazingly wide variety of follow-up reports by the Royal College of Physicians (1999), the Royal College of Pathologists (2000), the Department of Health (2001a, b), and the Medical Research Council (2001). Early in 2002 another official body, the Retained Organs Commission, published a consultation document which sought views on 'the respectful use and reverent disposal of unclaimed and unidentifiable organs and tissue, and a possible framework for the regulation of museums, archives and collections of human organs and tissue' (p.3). All these reports aim to ensure that adequate informed consent is obtained for the retention of body parts and human tissue at post mortem, via appropriate regulations.

The world in which we now find ourselves is a dramatically different one from anything that has existed in our life times. The expectations of today are radically different from those of 40 years ago. The question is: how do we cope with them? It is easy to stand behind the inadequate legislation of the 1960s or 1970s, and state that the role of informed consent

was not as clear then as it might have been. That may be true, but we also have to think and act ethically.

Searching for a Balanced Perspective

These incidents bring into view the sometimes conflicting demands of medical research against efforts to protect the dignity of human beings and demonstrate respect for human tissue. These are legitimate competing interests, and it should be our intention as a society to hold the two in tension. Unfortunately, interest groups frequently fail to do this, forcing an invidious choice between supporting scientific investigation or upholding informed consent. This stark choice will serve no one's long-term interests, since it pits responsible scientific research against serious ethical decision-making, both of which will lose out. Unfortunately, the high-profile incidents referred to above precipitate this conflict: medical research has been carried out in an unethical manner; therefore, the medical profession and scientists work unethically; therefore, medical research is not possible in an environment that upholds high ethical standards.

I reject the simplistic facade of this argument. But how can it be dealt with? One approach is to allow the research use of material already in existence but prohibit acquiring any new material. A classic illustration of this is President Bush's compromise position over human embryonic stem cell research. It is unethical to use human embryos in this way; nevertheless, those cell lines already in existence can be used, as long as no new ones are produced (National Institutes of Health, 2001). This political compromise leaves unanswered the question of how use of these cell lines can be ethical, if the production of new cells lines is deemed unethical. Similarly, few ethical concerns have been expressed over the use of archival stored human material in museums, even in the absence of informed consent. Lack of legislative clarity 40 or more years ago seems to justify this lack of concern, even when major concerns abound over obtaining recent material without adequate consent (Retained Organs Commission, 2002).

Responses of this nature allow researchers access to some human tissue (that already in existence), but they fail to address the pressing matter of how tissue will be obtained in the future. There is no question that previous practice which ignored informed consent was unsatisfactory, even if the practice conformed to the generally accepted standards of the day. As we look ahead to future practices, we have to map a course

which recognizes the dual importance of scientific and clinical research on the one hand, and informed consent and allied ethical considerations on the other.

In the absence of these dual responsibilities, disciplines like pathology will all but disappear, with major negative consequences for clinical medicine (Lilleyman, 2002). In addition, many branches of biomedical research will be seriously impeded, if not stopped altogether. This is not a plea for unregulated research, since there are too many recorded instances where biomedical scientists have run roughshod over patients (Cartwright, 1988; Bromberger and Fife-Yeomans, 1991). However, a society which accepts the crucial role of research within an ethically enlightened environment will welcome good auditing practice and research, alongside serious ethical obligations to patients.

Ethical Guidelines

Some recent documents (Department of Health, 2001b; Retained Organs Commission, 2002) point to the significance of the following ethical principles in relation to the retention of body parts.

- *Respect*: treating the person who has died and their families with respect.
- *Understanding*: for many parents and families their love and feelings of responsibility for the dead person are as strong as they were during life.
- *Informed Consent*: permission is sought and given on the basis of fully informed consent.
- *Time and Space*: families need time to consider agreeing to post mortem and the donation of tissue and organs.
- *Skill and Sensitivity*: towards the needs of the relatives.
- *Cultural Competence*: awareness of differing attitudes towards post mortem, burial and the use of organs.
- *Gift Relationship*: balance should move from 'taking' and 'retaining' of organs to 'donation'.

While these excellent guidelines protect the interests of the deceased and the grieving families, they fail to address the interests of both medical professionals and researchers.

Accessing Tissue for Research

Means need to be found of determining the relative weight to be assigned to the stringency of the informed consent required for the use of whole bodies, large body parts, and smaller

samples of human tissue. In this connection, the following issues may be worthy of further consideration.

Relative Symbolism of Different Body Parts

Whenever concern is expressed at the removal of organs from cadavers without consent, attention is mainly focused on organs like the heart and brain (Department of Health, 2001b). It has also been noted that retention of small tissue samples does not appear to have the same cultural and emotional significance as retention of larger tissue specimens or whole organs (Ashcroft, 2000), while pathologists contend that the brain, kidneys and limbs are perceived in a different way from blood samples or sections of bones (Roberts *et al.*, 2000). If this is the case, it is inappropriate to regard all organs and tissues as belonging to a homogeneous population. Some samples have far greater symbolic significance than do others. This argument can be taken further when tissue blocks and histology slides are included, since the small amount of tissue in these has been largely replaced with paraffin wax or chemicals (Retained Organs Commission, 2002). While these processes have not removed them entirely from the realm of human tissue, they occupy an ambivalent position.

Society's expectations and regulations should reflect these differences. For instance, while stringent consent should be required for the removal of a brain, a far less demanding form of consent should apply to the retention of pieces of omentum from the abdomen or slides of sections through an organ like the kidney.

Gradation of Biological Value

This symbolism reflects a gradation of biological value from tissues vital to the continued existence of an individual, through to those of little significance for human functioning. Unless a demarcating line is placed somewhere along this continuum, it becomes impossible to make any ethically relevant distinction between, say, retention of the brain and retention of fibrous tissue. Clinically, there appears to be a gap of major clinical significance between essential but replaceable organs (heart, kidneys) and non-essential organs (spleen, appendix, one kidney). This corresponds to a symbolically significant gap. While this gradation applies during life, it also has relevance after death. Indeed, it would be strange if an organ or tissue of little biological value for a living human being came to assume far greater significance to a cadaver (and relatives).

This gradation pays no attention to either essential, irreplaceable organs (brain), or the whole body – the still born or late fetus. These stand alone, having an immense symbolic and biological significance. Consent for their retention should be obligatory.

An interesting consideration is posed by research on human embryos. Issues raised by research in this area are not usually considered alongside issues raised by the retention of body parts, and yet the powerful symbolic overtones of embryo research have led to major opposition to it. When this is the case, practically no distinction is being made between the blastocyst and the fully formed human body. By-passing the developmental continuum leads to immense problems akin to those encountered in the body retention realm, and these might profitably be explored within the same framework.

Origin of Tissue

Tissue and organ parts are routinely removed at operation and are disposed of as clinical waste. Since the tissue has been removed in an attempt to improve the quality of the patient's life, it might be argued either that the patient has no interests in any unwanted tissue, or if there are some interests in it, use of such tissue for research purposes is justified since it is a form of gratitude for the treatment received. Either way, consent should be of a weak variety (Jones, 2000).

The most a post mortem can do for the deceased is throw light on reasons for the death – primarily it will assist the medical profession in improving its diagnostic abilities. Consent for a post mortem alone is, therefore, consent only for those procedures required to establish cause of death, and not for the removal of additional organs or tissues that might be useful for other teaching or research purposes. In this sense, small tissue pieces should not be removed at post mortem without consent, although if these tissues are low on biological and symbolic scales, the ethical significance of removing them without consent is minimal. Nevertheless, it would be wiser to err on the side of consent.

An obligation often overlooked is that of attempting to obtain consent. If informed consent is given priority, similar priority should be given to efforts at seeking consent for a post mortem and/or the removal of tissues for teaching and research purposes. There is no virtue in failing to conduct high quality research simply because no serious efforts have been made to obtain appropriate consent. The potential value of human

tissue for an understanding of human disease is too great to forego concerted efforts in this direction.

Societal Values

It has been evident to the anatomical community for many years that what can or cannot be done with, and to, human cadavers is dependent upon that which a particular society allows. When that has not been the case, as in early British society (Richardson, 1988; Sawday, 1995), anatomy and anatomists fell into disrepute and became outcasts within society. Over recent years, people in countries like New Zealand and Australia have been willing to bequeath their bodies, since this is seen as a means of aiding medical science (Fennell and Jones, 1992). Encouraging as this is, it is also a reminder that the supply of bodies and human tissue is dependent upon the goodwill of the public, their positive perception of the medical profession, and the high value placed on medical research.

These perceptions can change, as evidenced by the widespread concerns raised over the lack of consent associated with the retention of body parts at post mortem. The double tragedy experienced by some affected people (Jones, 2002) is not only a tragedy for them, but for pathology as a whole. This emphasizes a salutary lesson – no profession has a divine right to plunder the human body, even with the best of intentions. The privilege of working with human tissue has to be earned by researchers and teachers alike.

There is a fine line between being given permission to utilize human tissue and refusal to access it. The freedom to undertake research on human tissue is no more a given than are the precise boundaries of informed consent. Both have to be elaborated and teased out by mutual discussion. Consequently, considerable ethical discernment is required by the medical profession, the members of which must be prepared to enter into the ongoing ethical debate within society.

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