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The organ retention furore

THE NEED FOR CONSENT

John R Bennett

It is doubtful whether any physician used the term 'organ retention' before two years ago. The study of whole organs (fresh, or preserved in jars) and histological slides has been an integral part of medical education for centuries, and every undergraduate medical school had a pathology museum of which it was often justifiably proud.

Things began to change when the mother of a child who had died after surgery at The Bristol Royal Infirmary saw a television programme in 1996 about paediatric heart surgery and requested her daughter's records. They showed that the child's heart had been retained, so she asked for it back. The Bristol Heart Children's Action Group was set up and discovered (in the words of the interim report of the *Inquiry into the management of children receiving complex heart surgery at the The Bristol Royal Infirmary*)¹ 'that tissue had ... been systematically taken at or after post-mortems ... The tissue had been removed and retained ... and used for a variety of purposes, including audit, medical education or research, or had simply been stored'. The actions so described probably seem unexceptionable to most doctors. The following paragraph explains the sequel:

'When the practice of tissue retention came to light in Bristol there was, both in Bristol and elsewhere, an outcry from parents. They sought information about whether tissue had been removed from their children. Once informed, some asked for organs and tissue to be returned for burial. In response, an extensive search was carried out in Bristol to discover what tissue had been removed, and once removed what had become of it. Parents were notified and, if they wished it, their child's tissue was returned to them.'

And later:

'The press and other media gave considerable publicity to the evidence of Professor Anderson to the Bristol Inquiry in which he described the various collections of tissue which existed around the country.'

No doubt with the best of intentions to show that such collections were normal, the unfortunate Professor Anderson happened to mention a large collection at Alder Hey Hospital, Liverpool. It was soon discovered that huge numbers of organs had

been built up between 1988 and 1995 by the Professor of Foetal and Infant Pathology, Dick van Velzen. The hospital was sluggish in responding to hundreds of resultant enquiries from parents, who formed a support group – Parents Who Inter The Young Twice (PITY II).

Pandora's Box was open. In late 1999, the Secretary of State asked the CMO of England to prepare an inventory of centres where tissue was held – an initial trawl suggested that 50,000 organs were stored in hospitals and universities in England and Wales. The Government also instituted an Independent Confidential Inquiry into the Liverpool matters, chaired by Michael Redfern QC². Its report (in January 2001) looked into the whole question of organ retention after autopsy, but also analysed what Professor van Velzen and his junior colleagues had been doing.

The Law and Ethics

There are many differences between law and ethics. The medical profession, while always being required to practise within the law, also has its ethics, often more demanding than the law. These ethics, often disseminated orally, have been increasingly codified, notably by the BMA and the GMC. Ethics (the word is derived from the Greek *êthos* – meaning 'usage' or 'custom') are rules based on law and on a consensus view of what is moral, appropriate, customary, and humane. They are prepared and written by the profession itself, but increasingly with advice from moral philosophers and ethicists, and with a consciousness of public feeling on certain matters. The bewilderment of many doctors about this whole organ retention affair is because most of the actions (branded in the media as scandalous, shameful, and macabre) were within the law and actually within the ethical code then current. Needless to say, the imbroglio has resulted in rapid and radical changes in the ethical advice, but it is sad that politicians – the legislators – seemed content to allow implications of illegality where none existed, after decades of failure to amend legislation on matters like death certification, coroners, cremation and related subjects. As the CMO's³ report states 'The law governing [organ

John R Bennett

MD FRCP,
Former consultant
gastroenterologist

Clin Med JRCPL
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retention] is unclear, ambiguous and ageing. [It] was ... poorly understood and, as a result, not applied well'.

The Law

For this summary I rely on a detailed analyses of the law contained in Appendix B of the Bristol Inquiry's Interim Report¹ and in the Royal Liverpool Children's Enquiry Report².

A coroner may order an autopsy, and in such cases the pathologist acts as the coroner's agent. There is no statutory requirement for the coroner to obtain consent, and indeed a coroner's autopsy may be conducted despite objections from relatives.

For a hospital post-mortem the Human Tissue Act 1961 provides that 'no post-mortem ... shall be carried out without the authority of the person lawfully in possession of the body'. A problem here is that the person lawfully in possession is not defined, but a note in Halsbury's Statutes indicates that in hospital the manager thereof is in lawful possession. There is no obligation to obtain consent. The person giving authority must 'make reasonable enquiries to discover whether there is any objection from the surviving spouse or any surviving relative and has no reason to believe that the deceased expressed an objection'. Nevertheless, for many years, actual consent has usually been sought and hospital pathologists customarily refuse to perform an autopsy without a form of consent signed by a relative.

There is no statutory requirement for results of the post-mortem to be given to relatives (though many clinicians and pathologists did so, spontaneously or on request).

The Alder Hey Report² is, however, pungent in its criticism of doctors' ignorance of the Human Tissue Act 1961 and believes that far more searching enquiry into possible objection to autopsy should have been made.

Retention of organs and tissue

Once an inquest is concluded and the verdict returned, the coroner has no further lawful authority. Therefore, as the coroner's agent, the pathologist also ceases to have lawful authority. Nevertheless he has a duty to remove and preserve material which bears upon the cause of death. '... once the coroner has become *functus officio* it is not clear what legal powers and obligations are possessed by the pathologist, who is often in physical possession of ... material'¹. Professor Green told the Bristol Inquiry that 'the prevailing view in the profession' was that such tissue was, in effect, the property of the pathologist and the department which has processed it. 'It is perfectly licit to use [it] for research purposes; it is perfectly licit to use that organ for teaching purposes, museum purposes'.

In 1994, the coroner in the Alder Hey affair was asked for a ruling on ownership of tissue remaining when the coroner's process was complete. He replied 'I do not know a definitive answer ... The right to possession of a dead body is vested in either the deceased, executor ... or in the person entitled to apply for Letters of Administration ... I think that any tissue

which remains after all necessary examination ... belongs to the person entitled to possession of the body. In over 25 years' experience, I have never had a legal representative ask for the return of such material and I cannot visualise any circumstances in which it would be likely'.

For hospital autopsies however, the 1961 Act provides for the removal and use of parts of a body 'for purposes of medical education or research' (S.1(1)). The Nuffield report⁴ enlarges on this by writing 'Provided that the terms of the Act ... are complied with, any part may be removed (save where the deceased has specified a particular part, in which case it appears that only that part may be removed). The part may then be used for the purpose indicated by the deceased or the person lawfully in possession of the body'.

So, in summary, it seems that retention of organs (other than those 'bearing on the cause of death') removed at a coroner's autopsy may have been customary but not strictly lawful, although after a hospital autopsy (for which relatives' consent is not required) it probably was lawful.

However, that there are ambiguities and uncertainties in the law is undeniable, as the Nuffield report⁴ pointed out in rather heavy legalistic phraseology. 'It is open for the courts to accept that removal of parts of a body, outside the terms of various statutes, can be justified at common law where such removal is for advancement of the public good. This would be of importance, for example, in the case of tissue removed for retention in an archive: unless archiving can be regarded as 'teaching or studying or researching' within the terms ... of the Anatomy Act 1984 ... (and, on one reading of the Act it may be so regarded), it could be unlawful to remove tissue for these purposes in the absence of a common law justification ... Clarification of the law ... would be desirable'.

Ethics

Ethical guidance in this area, as usual, was not based exclusively on law. As indicated above, seeking and confirmation of consent for the hospital autopsy goes beyond statutory requirements. A phrase often present on such forms was that 'it allows us to remove tissue for laboratory investigations which are not possible during life'.

Notwithstanding the legal position of the coroner's autopsy, in 1990⁵ the Royal College of Physicians said 'discarded or stored specimens are not in law the property of the patient', and in 1996 advised that 'The anonymous use for research ... of tissues removed at ... autopsy is a traditional and ethically acceptable practice that does not need consent ...'. It added: 'There may be legal constraints and it remains unclear to whom such samples belong in terms of beneficial ownership'.

The 1995 report of the Nuffield Council on Bioethics *Human Tissue – ethical and legal issues* (chaired by Sir Patrick Nairn)⁴ prophetically stated: 'The ethical and legal bases ... have rarely been explored properly and systematically. What tends to happen is that, from time to time, particular matters exercise public attention; and if it appears that the law is unclear, or inappropriate, and the matter is sufficiently compelling, specific

legislation or professional codes of practice, or both, are introduced to deal with particular problems. *Public concern and outcry sometimes foster legislative or other regulatory activity*' (my italics).

There seemed to be no ethical guidance to suggest that relatives should be informed of any retained organs or tissue.

Custom and practice

I referred in the introduction to the experience by all doctors of the frequent use of whole organs or tissue specimens in teaching and also in research. To us it is so commonplace as to be quite unremarkable, and few doctors will have been as surprised as those in authority when the Chief Medical Officer discovered that NHS hospitals and medical schools hold about 105,000 organs and body parts – about half of them collected in the past 30 years. If all human biological material were included (tissue samples, blood, etc), the number would be greater: in the USA there are over 282 million specimens stored³.

The puzzlement and almost mute defencelessness of the British medical profession as further violent media insults rained down on them, arose. This was first because it has been so customary to them and yet appeared quite unknown to an ostensibly intelligent and well informed section of the community; secondly, that so much importance appeared to be attached to the wholeness of the corpse when buried or cremated. That the 'victims' were children rather than adults doubtless raised the emotional temperature, but it does seem that public opinion has moved more quickly to a position of requiring detailed information and more explicit consent for every medical action than we, as a profession, had realised. 'Society's attitude to death and to the care of the human body after death have evolved with time, partly reflecting cultural diversity. At the same time, the public and patients no longer wish important decisions to be taken by professional staff on their behalf, but expect a full informed partnership in all such decisions'⁷.

The CMO's report³ states that there was 'a failure by many doctors ... to empathise with parents who have faced the devastating loss of a child and the failure to recognise that a parent feels love and the need to protect a child, even after death. The fact that for many parents the essence of a child is contained in organs such as the heart or the brain engendered feelings that the child had been violated and that the parent had not been able to protect him or her'. Having read all the written submissions to this inquiry and listened to all the oral statements, I am unaware of any evidence of such a lack of empathy (or sympathy) with parents; that parents regarded the 'essence of a child' to be contained in certain organs probably did escape many doctors' attention – and probably would escape many theologians' attention, too.

But why was there such an uproar? The fact that they were children's organs which had been removed and retained is relevant: the death of a child will always linger as a painful memory to a parent, and they will have been awoken with a jolt. Many others cried out too, and it may be that, for the first time,

non-medical people had been brought face-to-face with the realities of the autopsy. Experience of autopsy brings detachment, and what John Hunter (in the 18th century) called 'a necessary inhumanity'; this is not the same as the callousness of which we have been accused. No doctor feels comfortable when a patient dies; telling the relatives is always difficult; to go on to request an autopsy usually seems an impertinent scientific intrusion into their bereavement. To go further and describe the details of post-mortem dissection and ask to keep some organs from the body of a person who, until a short while earlier, had been a living member of their family, is to accentuate that intrusion to a point which many doctors feel unacceptable.

The Redfern Inquiry² directly quotes parents' confusion and inability to comprehend what was being asked for consent to autopsy. 'Not a lot that was said actually went in ... I signed the paper through tears and just wanted to grieve at home'. 'When they ask you to sign the form you are in so much turmoil you could sign your life away ...'. Every doctor recognises the scene with sympathy. Despite this, the report is uncompromising in its condemnation of such attitudes. 'Is such a formulation a proper one under the Human Tissue Act 1961?' 'It is a sad fact of life that many important decisions have to be made when we are upset ... when we would wish to turn away'. It quotes the Polkinghorne Report of 1989 on consent: 'we are conscious of the need to avoid distress but are even more strongly opposed to formulations which disguise the reality of what is to take place'. Yet how can it be done better? There is no time for prolonged reflection: there has often been criticism if any autopsy delays the funeral. Will the proposed bereavement advisers do better than the doctors? It seems unlikely. There has already been a shift to having lay administrative staff make the request, and their success in achieving consent has been low. Who can possibly make such a request more appropriately and more compassionately than a doctor who has been caring for the patient in life? That *was* paternalism (a desire to protect and guard as well as guide) or (the definition chosen by the Redfern Inquiry) 'the policy of restricting the freedom and responsibilities of one's dependents in their supposed best interests' but that word is now always used pejoratively of doctors.

Of course, the apparently purposeless acquisition of organs at Alder Hey was inexcusable, and the Redfern inquiry's 500 pages² leave few of the involved parties unscathed; many of them now face a GMC inquiry, having been reported to that body by the Chief Medical Officer. But we must question the noise and anger which followed. For the Secretary of State to consider the events – which caused no physical injury, no death – as 'the worst disaster to befall the NHS' is disproportionate.

The failure of doctors to request specific consent for the removal of organs and to inform relatives of such removal and retention has been caricatured as arrogant, paternalistic, unfeeling, ghoulish, and as organ hoarding. Few of us would plead guilty to such charges.

The profession in general, and some individual doctors, have been dealt with harshly over this matter, particularly by those politicians, lawyers and health department officials who used the wisdom of hindsight in reacting to public and media

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clamour, while showing little awareness of the great practical and emotional issues involved, and with an abject failure (particularly on the part of the parliamentarians) to acknowledge the shameful deficiencies of the law in these matters, warnings about which they had chosen to ignore.

The future

What, then, of the future? Can we see the consequences?

Legalistic practice and consent

One thing is absolutely clear from all the high-minded advice and instruction contained in the various reports. Doctors are expected to have a detailed knowledge of the precise wording of all legislation governing their practice, and also of any gloss placed on those statutes during the parliamentary debates preceding their enactment (Mr Redfern and his colleagues leave no room for doubt about that). Furthermore, they must comply with all additional advice and guidance from all authoritative sources.

In particular they must be scrupulous in obtaining consent for everything they do to or for a patient, living or dead, explaining in detail all that is to be done to them (or their relative), notwithstanding the distress this will often cause to the patient or relative, let alone the doctor.

It is for cleverer minds to show how that fits with our additional duty to be sympathetic or empathetic – but it seems that strict compliance with the law is considered more important.

Autopsies

The hospital autopsy has almost disappeared – from 24,000 a year in the 1970s and 1980s to 14,000 in 1999; it is hard to see how it can survive. Professor Lilleyman (President of the Royal College of Pathologists) says that in calmer discussions with parents of PITY II and National Committee Relating to Organ Retention (NACOR) ‘they acknowledged the immense value of post-mortem studies of retained material and have offered to help us effect change’. A lay researcher who talked to most of the Bristol parents stated that roughly half ‘would have been willing to donate organs ... if it might have saved other patients’ grief⁸. Nevertheless the process of obtaining consent will become so lengthy, cumbersome and emotionally fraught as to deter any but the most intent searcher for truth. The explanatory document recommended by the Royal College of Pathologists⁷ is over four closely printed pages long (including glossary), followed by a consent form with sixteen tick-boxes. Coroners have already shown greater reluctance to order autopsies. In neither group will it be easy to retain any organ or tissue, even briefly, and such acts will always need lengthy explanation and documentation, including uneasy discussion about the eventual fate of such organs or tissue specimens.

Museums

The Retained Organs Commission has already started work, and

will cause huge labour to be invested in cataloguing and sometimes returning all retained tissue in the UK. The Royal College of Physicians has already owned up to the possession of the Harvey Tables – the 17th century wax impregnated dissections from Padua. What will happen to the great and important collections in other colleges, universities and hospitals cannot be predicted.

Death certification

The Shipman case will lead (at last) to improvement in the process of death and cremation certification, and in March 2001 the Home Office announced an ‘urgent review of all matters relating to coroners’. How the expected zeal for better information about causes of death will match the obstacles to autopsy and tissue examination remains to be seen.

Organ donation

Existing problems of supply of organs for transplantation (heart/lung transplants fell 30% from 423 in 1995 to 290 in 2000) have been worsened by the adverse publicity, the public having been persuaded that all cadavers should be interred or cremated intact, regardless of benefit the removed organ might confer.

The Royal College of Physicians and the Royal College of Pathologists have advocated a programme of education and information to diminish the superstitious fears of organ donation and of autopsy, but there is no sign of a government response.

Donation of bodies for anatomical dissection

Although anatomy plays a smaller part in medical undergraduate education than it once did, it remains important. 1,000 people a year bequeath their bodies under the Anatomy Act³. It is too early to know whether this will change but the furore is unlikely to help.

Retention of organ and tissues removed surgically

By the act of consenting to surgery patients imply their desire to be rid of the offending organ or tissue. The legal ownership of such removed organs is quite unclear⁹, but they must make up a proportion of the organs counted by the CMO. One can only presume that, in the present climate, specific permission will have to be sought from the patient for preserving the tissue in any form, and also for their chosen method of disposal.

Retrospective research on stored tissue

Much useful research has been carried out on stored tissue specimens: a current example is work by Jeffery Taubenberger on influenza, using blocks of tissue taken from patients who died in the 1918 pandemic¹⁰. It seems improbable that such work could be done in future. Clinical geneticists envisage severe obstacles to genetic counselling if stored surgical or autopsy tissue is unobtainable¹².

Litigation

NACOR is reported to have applied to the High Court for a group litigation order for compensation to families of patients of the Leeds Teaching Hospital Trust, whose organs were retained by hospitals without informed permission. The report states that it is intended to 'pave the way for claims relating to 134 hospitals across Britain'. A solicitor, Mervyn Fudge, said 'I am sure the rest of the country does not want the perception that justifiable claims are being left behind while Alder Hey progresses'.

Conclusion

This has been a difficult business for the medical profession. I believe we have been victims of poor and badly applied law, and have been let down by one aberrant pathologist. Our desire to shield patients and their relatives from some of the more distressing aspects of illness and death has been pejoratively derided as paternalism. The long-standing intention to learn and teach, even after a patient's death has been debased, in many commentators words, as morbid curiosity or worse.

Can good come of it all? There have been signs in later media opinion that some writers see the dangers to education and research of stringent controls on autopsy and tissue retention. Perhaps there will be a possibility of explaining to the public why they are important. The clearest outcome is that *consent* is an issue of the greatest importance to patients and relatives, and all doctors need to recognise and act on that appropriately.

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Address for correspondence:

Dr John R Bennett, Kingspring House, Vicarage Lane,
Long Compton, Warwickshire CV36 5LH
E-mail: jrbennett@dial.pipex.com

Box 1. Response from the Royal College of Physicians of London to the Chief Medical Officer's Summit

Retention of organs and tissues following post-mortem examination

1 The main issues

It must be recognised that the retention of organs and tissues has been a common practice, worldwide, for centuries, and has formed an essential part of medical education and research, both undergraduate and postgraduate. The frequency of autopsy has declined over the past three decades to the detriment of education, and further obstacles to the use of autopsy are to be deplored.

It is also regrettable that there have been implications that such storage of organs and tissues has been thoughtless, cavalier or macabre.

It is true that specific consent for the retention of organs and tissues was not usually sought. This was not because of an intention to deceive or conceal the purpose, but because it was assumed that acceptance of such actions was implicit in the consent given to the process of autopsy. We do not believe that most people, giving consent to autopsy, believed that every piece of tissue was returned to the cadaver prior to burial or cremation. Most doctors would consider it kinder to omit such discussions in order to avoid further distress to relatives.

In the strongly emotional climate surrounding circumstances of cardiac surgery at Bristol Royal Infirmary and Alder Hey Hospital it has become clear that some members of the public believe past practices to have been wrong and unethical. In consequence, practice has already changed considerably, but the concerns raised clearly indicate a need for specific change.

2 Suggested changes

- a When consent for autopsy is sought from relatives of the deceased, or when the coroner orders an autopsy, an indication must be given in writing to the relatives that tissues or organs may be retained for purposes of research and education and to allow further examination of the cause of death and the disease process.
- b When such retention occurs then the next-of-kin may be given an indication in writing of what tissues or organs have been taken, if during initial autopsy consent they have indicated a desire for such information. Where whole organs have been retained the next-of-kin should be given the opportunity to give further consent to their permanent retention (if desired), and if this is withheld make a clear request for appropriate disposal of the organ, including subsequent burial or cremation [It is clearly impossible to obtain consent in advance of an autopsy as the selection of organs retention can only be judged at the time of examination].
- c Public education about the benefits of autopsy and the study of retained tissues and organs needs to be increased and improved in collaboration with appropriate professional bodies. The emotional responses (however understandable) of the last few years need countering by appropriate explanation lest the progress of medical education and research be damaged.