

letters

TO THE EDITOR

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The organ retention furore

Editor – John R Bennett rightly stresses the need to gain informed consent before taking body parts from the dead (*Clin Med JRCPL* May/June, pp167–71). But he ducks the uncomfortable necessity to acknowledge that unconsented retention of organs is wrong.

Public affront at medical behaviour derives not from hostility to post-mortems, or the use of bodily materials for teaching or research, but from the fact that the process has been carried out by subterfuge, on a nationwide basis.

It is not as though doctors who took body parts from the dead at Bristol, Alder Hey and everywhere else, were ignorant of the existence of the next of kin. It is surely not unreasonable to suppose that 'reasonable efforts' to obtain consent might include looking in patients' notes, and – as in transplantation – body parts should not be taken without asking.

My work, which John Bennett cites, suggests that among parents at Bristol there was strong support for a process of understanding what went wrong with their children's operations; and a strong desire too, that lessons be learned from these deaths which might prevent suffering to other parents' children. The likelihood that consent *could* have been obtained was high. But it has been customary, and in John R Bennett's view, ethical, not to seek it. Guidance from Royal Colleges endorsed the removal and acquisition of organs, sometimes entire viscera, without asking.

It seems to me that despite the prevalence of ethicists and lawyers, the medical professions have lagged well behind the public in this important area. We know that hostility towards dismemberment and dissection has existed in Britain since time immemorial. Coercive legislation enforcing dissection upon murderers after execution, and subsequently upon the workhouse poor, meant that few people (even doctors) ever donated their own bodies for dissection. However, the creation of the National Health Service in 1948 engendered a new public generosity towards medical endeavour, and a significant growth in the number of whole-body donors.

Today we have donations sufficient to the needs of anatomical teaching and research. Our blood transfusion service is run on a similarly voluntary basis.

Transplantation developed after World War II, when whole-body donation was rising. Although we hear constant complaints about shortages of organs for transplantation, the British public has in fact been wonderfully generous in donating organs: in Japan, by comparison, such donations are still rare.

Yet despite significant public generosity, consent for the donation of bodily materials at post-mortem has rarely been sought. Pathology as a discipline apparently proceeded in a pre-NHS mind-set, broadly supported in this by other medical disciplines. The real nature of post-mortem examination has been assiduously kept secret, as has the quantity of material removed from the dead, and its fate: whether this be the lab, the archive, the waste bucket or the pharmaceutical company.

The organ retention furore has lifted the stone of ancient abuse, and we are witnessing a might squirming and wriggling. I have myself heard some doctors assert that next-of-kin were kept in ignorance to spare their feelings, yet complain that the public are ignorant of the needs of science. The Bristol and Redfern reports, and the CMO's splendid Summit, have made clear that not all doctors share such views.

John R Bennett's paper recognises that consent will have to be sought in future, while attempting professional exoneration for the past. But it is fatuous to pretend

that a hospital manager or pathologist could ever have had a greater entitlement to possess a dead child's organs than the next of kin.

I hope that, eventually, all medical professionals and their Colleges will recognise what the public already knows: honouring the human rights of patients and next of kin is as integral to medical progress as any scientific discovery.

RUTH RICHARDSON
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In response

Ms Richardson does not seem to have understood my points, and I would ask her to re-read the article and look at the *facts*. Leaving aside the Alder Hey events (which no-one defends) almost all the actions of doctors over the centuries has been lawful and ethical. The main possible exception is retention of organs after coroner's autopsies, and even there the law is uncertain. Yet all the clamour from public, politicians and media strongly implied that doctors had regularly been acting illegally and unethically and these accusations are most unfair. They are made with all the wisdom of hind-sight.

The second false accusation, which Ms Richardson repeats, is that doctors have acted 'secretly' or 'by subterfuge'. This is quite untrue. The existence of large collections of preserved organs is surely a well-known public fact. The great museums are not shut away from public view; coroners (the guardians of proper behaviour in regard to death) were fully aware of it; surely everyone in the country has seen 'Doctor in the House'. The reasons that explicit consent for the retention of organs was not obtained are two-fold. Firstly, it was not required by law or ethics, and secondly (as I tried to explain in my article) it seemed kinder to relatives not to add to their understandable and inevitable distress by discussing what many laymen would feel is a somewhat gruesome topic.

Ms Richardson is not fair in describing the retention of tissue from properly authorised autopsies as 'an ancient abuse'. As an historian can she cite a single reference to demonstrate any public disapprobation in the 20th century of this longstanding and important educational practice? Nothing in the parliamentary

debates on the 1961 Human Tissue Act or in subsequent expert committee reports on tissue storage indicates it. If it was such an abuse, how did our legislators come to ignore it and leave the law in such an untidy and unsatisfactory state?

However, in this whole matter emotion and media attention-seeking has taken precedence over common sense. There will now be change – but as I seriously asked, will it *overall* be for the better?

JOHN R BENNETT
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Ethical approval for health research

Editor – The article by Coker and McKee (*Clin Med JRCPL* Jan/Feb 2001, pp197–9) highlights the importance of developing sound ethical review for biomedical research. We wish to draw attention to some important activities regarding ethical review in Central and Eastern Europe not mentioned by the authors. More thorough research and direct involvement in the region shows that, as in Western Europe, the role of ethics committees is not to provide ‘ethical supervision’ of biomedical research nor to act as fraud-busters. Rather, well functioning ethics committees are there to provide ‘consideration, comment, guidance and, where appropriate, approval’ on research protocols. Similarly, the global need for greater public involvement in bioethics is not a burden that needs to be squared on the shoulders of ethics committees.

We are concerned that no reference has been made to the activities carried out by the Council of Europe (CoE), partially in collaboration with the European Commission. The Demo-Droit Activity on the Ethical Review of Biomedical Research (DEBRA) at the Council of Europe has been active in developing both a regional framework for ethical review as well as in-country activities. Under the auspices of DEBRA, bilateral meetings have been held in most of the ‘transitional economy’ countries with the participation of many Western European experts. The launch of this focused programme took place at a meeting at the Royal College of Physicians of London in 1997, at which delegates from many of the Central & Eastern European countries were present. The RCP Guide-

lines on ethical review¹ were presented as well as the *Guidelines and Recommendations for European Ethics Committees* (EFGCP)². The meeting was followed by a Special Issue of the *Quality Assurance Journal*³ devoted to current issues in this field and again made available to relevant personnel in all participating countries.

During 1997–2000 in-country meetings were held in Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, the Russian Federation, Slovakia, Slovenia, and Ukraine. Further initiatives are planned for 2001–2002⁴. Numerous countries have participated in study visits to Western Europe, some to the UK, and have received legislative expertise. The participation of Central and Eastern European Member States in COMETH (Standing Conference of European National Ethics Committees) has also been supported by DEBRA with funding provided by the Council of Europe, the European Commission, and the Kingdom of Norway. A partial overview of these activities was published last year in the book *Ethics Committees in Central & Eastern Europe*⁵.

The Council of Europe, through the Steering Committee on Bioethics (CDBI), participated in the drafting of the *Operational Guidelines for Ethics Committees that Review Biomedical Research*⁶, published in March 2000 by the Special Programme for Research and Training in Tropical Diseases (TDR) of the World Health Organisation. Turkish and Russian were among the first translations of these global Guidelines, that also function as the key international reference document for the recently adopted UK guidelines for research ethics committees⁷. Poland and Georgia are in the process of translating these guidelines, as are other countries in the region.

In March of this year, the World Health Organization collaborated with the European Forum for Good Clinical Practice (EFGCP) and the Institut Pasteur in St. Petersburg, on a workshop on ethical review in Russia and the Confederation of Independent States. The Council of Europe also assisted with this workshop. This led to the formation of the Forum for Ethics Committees in the Confederation of Independent States (FECCIS). This Forum

is now assisting, from within the region, in the building of in-country infrastructure as well as cross-national understanding. FECCIS is supported in its work by the recently established Strategic Initiative for Developing Capacity in Ethical Review (SIDCER), an overarching framework for established in Asia & the Western Pacific, Africa, and Latin America as well as FECCIS.

While our interest in sound ethical review is continually deepened, so too is our understanding of how ethical review is practiced in different countries. The differences in economic and political structures between Central and Eastern Europe, on the one hand, and Western Europe, on the other hand, do explain some of the challenges to ethical review as we cross boundaries. At the same time, we should be mindful not to insist too much on these differences in explaining practices or accounting for ‘development’ in ethical review. European countries across the board have largely common needs and interests concerning the ethical review of biomedical research; they also share much the same regard for best practices along with many of the same frustrations. No one country is a model, nor is any one side of the divide a shining example. We can all learn from one another.

References

- 1 Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research involving human subjects*. London: RCP, 1996.
- 2 European Forum for Good Clinical Practice. *Guidelines and Recommendations for European Ethics Committees (revised edition)*. Brussels: EFGCP, 1997. [Available at www.efgcp.org].
- 3 Crawley FP (guest ed). Special Edition: Ethics and Quality Assurance in Clinical Trials. *The Quality Assurance Journal* 1997; 2:4.
- 4 Information about the CoE DEBRA programme is available from peteris.zilgalvis@coe.int and from the CoEthics website <http://www.legal.coe.int/bioethics/gb/html.ethique.htm>. See also: Zilgalvis P, Crawley FP (guest ed). An international dialogue in research ethics: the experience of the Council of Europe. Good Clinical Practice in a global research setting: achieving best practices in ethics and science. The Millennium Issue. *Good Clinical Practice Journal* 2001; 6: 25–7.
- 5 Glasa J (ed). *Ethics Committees in Central and Eastern Europe*. Bratislava: Charis, 2000.