Editorial

Biomedical ethics in Europe – a need for the POBS?

Raanan Gillon *Imperial College Health Service and St Mary's Hospital Medical School/Imperial College, London University*

In our first issue in the year of the single European Market we publish three continental European contributions on the theme of a more co-operative European approach to biomedical ethics – our own contribution to a single European market in biomedical ethical ideas. Two of these papers, Dr Quintana's from Spain and Judge Byk's from France, discuss the proposed European Convention on bioethics – a project not of the European Commission but of the Council of Europe – while Professor Riis, from Denmark, ranges more broadly in his discussion of medical ethics in Europe.

Perhaps unexpectedly, it is the Council of Europe and not the European Commission or European Parliament that is trying to 'harmonise' European rules and regulations for bioethics – and unsurprisingly, the attempt seems likely to prove controversial. As Dr Quintana points out in his guest editorial, countries do not like interference with their democratically reached socio-ethical decisions and while there is much that is positively to be welcomed in the new proposed convention, some passages seem likely to be unacceptable to certain countries. In particular, countries, including the UK, which have legalised abortion and embryo research are unlikely to be happy with the proposed wording of article 1, which, it is understood, declares that the convention and its protocols 'are designed to protect the dignity, identity and integrity of human beings, and guarantee all individuals, whatever their nationality or residence, the respect of their rights and fundamental freedoms with regard to the applications of life sciences'.

If the proposed wording is to be taken seriously there is no plausible way in which abortion and embryo research followed by destruction can be acceptable under the terms of the proposed convention (for whatever else can be said about them neither can be said to protect the dignity, identity and integrity of the human being that perishes). Alternatively the proposed wording is offered as some sort of a fudge whereby signatory nations who wish to continue to permit these activities will be assured that the European Court of Justice will rule that human fetuses and embryos are not human beings nor human individuals for the purposes of the convention.

Neither alternative is satisfactory. In the contemporary moral debate about abortion and embryo

research *neither* side generally denies the status 'human being' to the entities in question and it is surely an anachronism for this great moral divide (about the scope rather than the nature of our moral obligations) to be fudged in a new *bioethics* convention, by equivocation over the term 'human being'. Would it not be far preferable simply to acknowledge that serious thinkers the world over differ about the attributes a human being must have for it to have a right not to be killed (or a 'right to life') and that this is a matter which the convention should leave for decision through morally informed democratic law making in the individual countries?

A second proposed passage in the draft convention should also give pause to potential signatories: 'In the application of life sciences, the interests and well-being of the individual should always prevail over the interests of science and the community at large'. Whether or not this absolute requirement of the Helsinki Declaration is appropriate in its original and limited context of biomedical research, if it were to be applied, as now proposed, to *any* 'application of life sciences', the consequences would surely be unacceptable for many societies concerned to *balance fairly* the competing claims of individual and society. For if this proposal always to give priority to the interests of the individual were to be taken seriously, breath or blood tests for alcohol levels, biological testing of specimens to identify rapists or indeed any other lawbreakers, and the application of the life sciences in general to apprehend criminals, or, for example, to establish paternity in disputed cases, would all be outlawed except where such methods were in the interests of the person to be identified.

Thirdly, the proposed bioethics convention, like its parent convention on human rights, would continue to ban 'discrimination'. Is it not time that the qualifier 'unjustified' was added? There are many circumstances in which discrimination is justified on grounds of sex, race, colour, language and so on. Only women are (quite justifiably) allowed to use women's lavatories; only patients of certain racial groups are (quite justifiably) routinely tested for sickle cell anaemia, thalassaemia and other racially-linked genetic anaemias. Health promotion concerning the risk of malignant melanoma from exposure to sunlight is routinely (and quite

justifiably) targeted at people with white skins; leaflets in a particular language are (quite justifiably) given only to those who read that language. There is nothing wrong with discrimination, only with morally unjustified discrimination. It may be too much to hope to amend the original Convention on Human Rights, but it is surely not too much to hope that a new convention on bioethics can add that crucial qualifier, 'unjustified'.

Finally, the hearts of medical researchers and members of research ethics committees all over Europe will surely sink at the prospect of yet another set of instructions concerning medical research – as is provided in one of the proposed protocols to the new convention. Why, it may be asked, is it considered necessary at all when the World Health Organisation, through its offshoot the Council for International Organisations of Medical Sciences (CIOMS), has just revised its own international guidelines on medical research? But if such an additional protocol really is deemed necessary it must surely be made the subject of extensive discussion with the various interest groups in each country. Several current proposals can be expected to generate controversy in this context, of which two are worth noting here. These are, first, the requirement in *all* cases of medical research for the 'informed, free, express and specific consent of the person undergoing it'; and, second, the requirement of compensation in *all* cases of loss and injury sustained as a result of participation in medical research, whether therapeutic or non-therapeutic.

Briefly, the first requirement is surely too stringent, and would seem to rule out, among other sorts of medical research, research into the fluoridation of water, much medical records research, all therapeutic research where patients make it clear that they do not wish to be told details of their disease, and epidemiological research such as the anonymous testing for HIV antibody currently carried out in the UK on the basis of presumed consent and an opportunity for subjects to 'opt out'. The question of what counts as *adequately* informed consent is indisputably a crucial moral issue for medical research; but the absolutist assumption that underlies this particular proposal for answering it in relation to *all* types of medical research fails to reflect the nuanced complexity and variety of other national answers that may be equally – or more – morally acceptable.

As for the proposal that *all* loss or injury sustained as a result of participation in medical research shall be compensated, not only does it seem to entail very large and unnecessary expenditure but it seems to do so on the basis of what on analysis is surely unjustified discrimination of the sort properly rejected elsewhere in the proposed convention. Thus non-negligent harm and loss would be compensated for patients participating in therapeutic medical research but not for patients sustaining them as the

result of ordinary medical treatment and investigation. This is unjust discrimination but its avoidance would then seem to lead inexorably, if unintentionally, to a general requirement for no-fault compensation for all non-negligent loss or injury sustained through any 'application of the life sciences'. The answer, it has been previously argued in these columns, is to distinguish between therapeutic and non-therapeutic research and to compensate for non-negligent harms and losses only in the case of non-therapeutic research interventions (1).

There is plenty in the proposed convention that is to be warmly welcomed, including the guaranteeing by law of human dignity, identity and integrity; the requirement that national independent multidisciplinary bodies should be set up to examine 'the fundamental questions raised by the development of life sciences', consult with the public, and publish opinions about appropriate solutions; the right to 'effective respect' for 'private and family life with regard to the life sciences'; and the extension of the agreed principles of the convention and its protocols into international law and co-operation. But the draft proposals must be thoroughly debated within each proposed signatory nation, and only those that are unanimously agreed should be left in. Far better to have unanimous agreement about fewer items than to have any part accepted either unwillingly, or perhaps worse, unwittingly.

Dr Quintana says he hopes that the convention will not be 'the lowest common denominator' – but lowest common denominators are values common to a range of disparate values, expressed at their simplest level. The Council of Europe would have cause for considerable pride if its proposed European Convention on bioethics succeeded in articulating at their simplest the common values of a wide range of signatory states across a wide range of ethical issues related to medicine and biology. There would be far less cause for satisfaction if it tried to impose or otherwise engineer rules to standardise the national fillings for the equivalents of bioethical sausages.

Instead it might emulate the European Community's political concern for subsidiarity and add the following moral common denominator to its decision-making processes: when, after morally informed democratic reflection, states disagree about some fundamental bioethical dilemma, unless there are strong moral reasons requiring unanimity of resolution their different decisions should be respected. It could be called the Principle Of Bioethical Subsidiarity, or POBS!

Reference

- (1) Gillon R. No fault compensation for victims of non-therapeutic research – should government continue to be exempt? *Journal of medical ethics* 1992; **18**: 59–60.