

Jonathan Montgomery
Professor of Health Care Law, UCL Laws
Chair, Nuffield Council of Bioethics

Presentation to the Presidential Commission for the Study of Bioethical Issues
Philadelphia 31 August 2016

Public Bioethics and the Virtues of National Ethics Committees

Thank you for this opportunity to participate in this exploration of the roles of national bioethics advisory bodies. It is a privilege to be here. I will speak partly on the basis of my service on various types of national bioethics advisory body in the UK and partly from my reflections as an academic lawyer who researches and teaches on bioethics as a governance practice.¹ National Ethics Committees play many different and distinctive roles in the moral consciousness of their states.

This paper considers dimensions of three such roles.

- (1) to represent 'ethics' to and in Government;
- (2) to help 'the people' to reflect on their moral positions and to support public thoughtfulness; and
- (3) to represent their nations in a global bioethics governance.

Each of them raises questions about the nature of the authority to speak, the basis on which their claims for their opinions to be taken seriously are founded, and the way in which they go about their business. I will use the complex pattern of the UK's approaches to draw attention to some of the issues.

National Ethics Committees and Government

Since the USA led the way with its first Presidential Commission, National Ethics Committees have become a firmly established feature of bioethics governance recognised in Article 19 of the UNESCO Universal Declaration of 2005. The 11th biennial Global Summit of National Ethics Committees, held in Berlin in 2016 was attended by NEC members from 83 different countries.² However, this apparent international consensus masks a significant variation in the roles and functions of such committees. Some are conceived as an integral part of executive government (USA). Others contribute to the legislative branch of government, such as in recent reforms giving the obligation to ensure the legislative process is bioethically informed to the French CCNE.

In the UK, there many bodies who play their part in the oversight of bioethical issues but the nearest equivalent of the Presidential Commission is the Nuffield Council on Bioethics, established in 1991. However, that Council is a non-government organisation. It has no

¹ J. Montgomery, 'Bioethics as a Governance Practice' (2016) Health Care Analysis 1-16.

² <https://www.globalsummit-berlin2016.de/>

defined or guaranteed channels of influence. In terms of the taxonomy used by Dr Jason Schwartz in his testimony to the 25th Meeting of this Commission it is perhaps best understood as ‘arms-length plus’ or even arguably ‘plus plus’. It’s position is informal, inexplicit, but for most purposes an aspect of the ‘establishment’ – reflecting our general constitutional framework.

The NCoB has no positional authority, no constitutional right to speak to Government on bioethical issues. Instead, in order to have impact, it has needed to establish a form of relational authority based on its reputation. The evaluation that we commissioned in 2015 suggested that stakeholders perceive that our work is influential in a ‘quiet way’ but usually takes some time to come to fruition. It was suggested to shape thinking and culture among opinion formers, but was not always communicated in a very accessible way, and was said to be reflective in style rather than providing precise recommendations that get quickly taken up. Almost all our reports do in fact include specific recommendations, targeted at specific bodies and followed up by the Council. However, any response is discretionary and one policy maker interviewed for the evaluation observed that we sometimes write recommendations like a parliamentary select committee even though we did not carry that authority.³ Despite this, we can show that our work has been directly and obviously influential in both executive and legislative actions, including very clearly in relation to the UK’s decision to make provision for the use of mitochondrial replacement therapies.

We believe that our influence arises from our ‘character’, ways of working and quality of outputs, as we set out in our strategic plan for 2012-16. We committed ourselves to set of values that should underpin our work. An *inclusive* approach that hears all voices but scrutinizes them for *coherence and rationality*, developing a position that is intellectually *rigorous* and consistent with the best available evidence. These foundations may give some clues as to the ‘virtues’ that a national bioethics commission needs to display. Three seem especially important

- (a) *Independence*, which the Council believes is core to its authority; independence in the sense that it is not beholden to, or under the influence of, others in the conclusions that it reaches or the topics that it selects for examination. The importance of this is in part a function of its particular funding mechanisms as two of its funders, the Medical Research Council and the Wellcome Trust, also fund research of the sort of technologies that bioethics commissions are asked to consider. Without independence, the Council can be accused of providing false assurance of the ethics of scientific advance. The third funder, the Nuffield Foundation, does not give rise to the same potential for conflicting interests. There remains an important sense of independence even here, however, which will be shared by the Presidential Commission. This comes from the fact that unless a national ethics committee’s deliberations move from an open mind to a conclusion, then it is hard to show the value that it adds to policy making.
- (b) *Courage*: to speak our mind even when this is unpopular. We have not shied away from criticizing national policies or approaches to current issues. Nor do we believe

³ Firetail, *Nuffield Council on Bioethics Evaluation* (2015) available at <http://nuffieldbioethics.org/wp-content/uploads/Nuffield-Council-on-Bioethics-Evaluation-2015.pdf>

that it is respectful of public opinion to accept it uncritically. Respecting people means challenging them if we conclude that they are wrong, but on the basis of reason not merely disagreement.

- (c) *Practical engagement*: to ensure that our activities engage with policy makers in a way that they will be likely to take on board. We have therefore aimed to understand the thinking behind current policy positions, connect our recommendations with the terminology that is being used, and to facilitate discussion through round-tables and workshops, supporting the development of follow-up position statements. We seek therefore to be engaged in conversations, rather than merely to commentate.

This last type of activity is not limited to new projects, and has led us to the view that part of our responsibilities is the curation of our body of past work and the use of it to inform policy and public discussions even where we have not established a specific working party. We have been reasonably successful in doing this in relation to policy discussions, but perhaps less so in terms of the wider public discussion.

National Ethics Committees and the People

The original terms of reference of the NCoB, currently under revision, were premised on a fear of public rejection of medical advances. The Council's work was 'to identify and define ethical questions... in order to respond to, and to anticipate public concern.' It was then to explore those questions 'with a view to promoting public understanding and discussion'. When I was interviewed for the position of Chair of the Council in 2011, I offered the view that public engagement was an area that the Council had neglected. This was, I thought, in contrast to the Government advisory body with which I was then serving, The Human Genetics Commission.

Since then, the NCoB has explored various ways of engaging with public debate; it has sponsored a video competition for young people, worked with poets. What it has not developed is an account of how public engagement connects with normative bioethical work. The work of the Commission in this area will be a really important contribution and is likely to inform thinking in the UK. Nor has the NCoB met the standards of openness and transparency that come from the constitutional expectations of a body such as the Commission. I want just to acknowledge those two elements of your work that I envy in order to spend time on two areas where I have observations from our experiences in the UK. These regard consideration of the past and future challenges.

(a) Past –truth and reconciliation and virtue of contrition

As an external observer of the USA, I am particularly struck by the continuing shadow of previous research controversies. There are considerable similarities between the exposure of research misconduct by Beecher in the USA and that of Pappworth in the UK. However,

more recently the emphasis on research governance as a response to ethical failures has been supplanted in the UK by concerns over non-feasance (the failure to do research), misconduct (which is characterized as a problem of compliance rather than uncertainty about what ethics requires), and mistrust of researchers (especially those working in or with industry). From a regulatory perspective, this is seen as a different type of challenge to those that have typically concerned NECs. The statutory remit of the Health Research Authority includes a requirement to promote proportionality in research regulation, but requires it to reinforce prevailing ethical standards. The legislative assumption is that research ethics is reasonably stable but regulation can be significantly improved.

The shadow of research scandals in the USA seems darker and the need to show that they are acknowledged and addressed seems stronger. The Commission's report in 2011 *"Ethically Impossible" STD Research in Guatemala from 1946 to 1948* clearly belongs in this territory. The best UK comparison for this is probably the organ retention scandal that came to light in 1990s. This involved the retention of tissue samples, some organs and in one gruesome case a whole head, which had been kept after post-mortem examinations on deceased children; retained without the consent or knowledge of their parents. This scandal led to a major public enquiry into the events, the establishment of the Retained Organs Commission to oversee the institutional responses to the recommendations and then a statutory regulator (the Human Tissue Authority) to administer the legislation that followed.

It is an important aspect of bioethics governance to provide a process for truth and reconciliation in relation to such past failures of bioethics. However, these are not necessarily areas that NECs are resourced or equipped to follow. They require different ways of working than is commonly on their agenda. In particular, they require detailed documentary analysis, judgments on personal responsibility and liability, and the ability to exercise historical insight to avoid anachronistic assessments. There are significant challenges in seeking to bring such activities within the remit of a general bioethics commission.

Having undertaken both types of work, my inclination is to keep them clearly separate. Amongst the benefits of the UK approach to organ retention was that it separated three components; the forensic investigation, administrative oversight of transition to good practice, and regulatory oversight. However, there are also benefits of using national bioethics commissions. Amongst them is the opportunity to display contrition on the part of the nation. This is significant as a matter of justice, but also to enable current issues to avoid being overshadowed by the past rather than informed by it. The dignity of a national commission makes this possible.

(b) *Future*: secondly, there is the question of how bioethics commissions address the chronological context of public interests. The origins of the Nuffield Council on Bioethics lie in an era of 'hostility to science... based more than anything on fear and ignorance'.⁴ There is also built into the prevailing understanding of that time about science education

⁴ M. Warnock, 'A National Ethics Committee: to meet the growing public demand for candour' (1988) 297 BMJ 1626-7

a rather patronizing assumption of public ignorance – what is sometimes described as an ‘informational deficit’ model.⁵ Both of these are associated with a ‘catch up model’ of the tasks of public bioethics – the idea that science rushes ahead of public deliberation, ethical reflection, and regulation.

Based on the UK’s recent experience of technological advance, the environment is now more complex. Our recent engagement with decisions about the use of mitochondrial DNA replacement therapies serves to illustrate three ways in which our picture needs to be revised.

1. The scientists were open about the importance of public consideration and sought to facilitate it well in advance of the science becoming clinically applicable. There has been plenty of time, about fifteen years in the UK’s public discourses, for ethical debate prior to clinical usage becoming technically possible.
2. Regulation, in the form of our Human Fertilisation and Embryology Act 1990 (amended in 2008), with a statutory licensing authority, was in place prior to the need for a decision to be taken on the use of mitochondrial replacement.
3. The desire to use the technology was driven by a partnership of affected families, researchers and clinicians. This was not a matter of clinicians wanting to try something out on unsuspecting guinea pigs but of families wanting the opportunity to use innovative therapies.

This situation rather flips the assumptions on which the Council was originally founded on their head. As we put it in a letter that I co-signed on behalf of the Council

The question that parliamentarians must consider is not whether they would want to use this technology themselves, but whether there are good grounds to prevent affected families from doing so. We believe that those who know what it is like to care for, and sometimes to lose, an extremely sick child are the people best placed to decide whether this technology is right for them, with medical advice and within the strict regulatory framework proposed. They have been waiting for the science for long enough. They should not have to wait for the law to catch up.⁶

The key points here are (a) that the case for using the technology has come from the people not the scientists and (b) that it is a case based on the right or freedom to benefit from science. In such a context, the role of national bioethics committees becomes as much concerned with the justification of regulation rather than the ethics of using technologies.

There are further implications to this aspect of the democratization of bioethics. The audience for guidance becomes patients as well as policy makers. The regulatory targets are different; something that is already apparent in participant-led research.⁷ The UK’s Human

⁵ K. Sykes & P Macnaughton, ‘Responsible Innovation – Opening Up Dialogue and Debate’ in *Responsible Innovation*, Richard Owen, John Bessant and Maggy Heintz (eds) (2013) Wiley

⁶ Prof Sir John Sulston et al, Letter, *The Times*, January 28 2015.

⁷ E Vayena, R Brownsword, S J Edwards, B Greshake, J P Kahn, N Ladher, J Montgomery, D O’Connor, O O’Neill, M P Richards, A Rid, M Sheehan, P Wicks, J Tasioulas. ‘Research led by participants: a new social contract for a new kind of research’ *J Med Ethics* 2016;42:216-219 doi:10.1136/medethics-2015-102663

Genetics Commission took a tentative step in this arena when it proposed an approach to direct-to-consumer genetic testing that aimed to create a set of quality standards on which it hoped consumers would rely and that providers would use to gain market advantages by being able to present themselves as reliable services.⁸ In this context, the principles of deliberative democracy become less applicable as a normative framework.

I have spoken about the role of bioethics advisory bodies in relation to two of the arms of Government; the executive and the legislature. One of the implications of the move away from regulatory catch-up and conservative public responses is the enhanced role of the third branch, the courts. Both the UK and Canadian Supreme courts have recently recast debates about physician-assisted suicide as a human rights issue. They have explored versions of the right to die that preclude bioethical debate in favour of considerations of liberty. Such an account has the potential to put a mainstream bioethical issue potentially beyond the competence of both executive and legislature, and presumably also beyond that of bioethics advisory commissions.

The Commission's previous session explored whether human rights might be a starting point for bioethics. That is a contentious and complicated issue that deserves exploration. My point here is that, it might be end of bioethics commissions because some versions of human rights discourse deny that the substantive issues are amenable to deliberative governance. In Europe, and especially in the UK, judicial oversight of debates over death and dying has structured the discourse so as to privilege arguments about protection of the vulnerable from abuse over those about the dignity of human life. Legalism of this type rules certain mainstream bioethical positions out of court.⁹ I have argued that in the UK this activity has typically been amoral as it constrains determines ethical issues by applying rules designed for different purposes.¹⁰ Any resemblance to bioethical reflection is accidental. It does not, of course, follow that this implication of one manifestation of human rights discourse means that there are not more fruitful opportunities for national bioethics commissions. My example was rather parochial. I fear this is also true of many other discourses of human rights and that claims of universalism are difficult to substantiate. However, the idea that we should frame bioethics in an international context, and possibly through legally binding instruments, was being discussed in the margins of the last Global Summit.

National Ethics Committees and the World Order

My final set of reflections therefore concern the role of national bioethics commissions in global governance. Here, there is a tension with the two earlier areas of activity. Those were nationally specific, concerning governments and peoples. Issues in health and health care

⁸ Montgomery, J(2013). Strategies of regulation: illustrations from the work of the Human Genetics Commission. In M. L. Flear, A. -. M. Farrell, T. K. Hervey, T. Murphy (Eds.), *European Law and New Health Technologies* (pp. 103-105). Oxford: Oxford University Press.

⁹ See J. Montgomery, 'The legitimacy of medical law'

¹⁰ J. Montgomery, 'Law and the demoralisation of medicine' (2006) LS. For a critique, see C. Foster & J. Miola

are dominated with local concerns about socio-economic conditions and delivery systems. Yet many developments at the cutting edge of medicine and science are increasingly international in nature.

There are technical and also normative dimensions here. To consider the former, we might think about mitochondrial DNA therapies and genome editing techniques. Here the scientific advances are being discussed collaboratively in many different countries, yet 'official' bioethics discussions are largely being conducted in parallel, with separate reports and regulatory responses (albeit that those conducting them within different countries are in conversation with each other). Thus, the UK the regulator (the HFEA) and NCoB have undertaken consultations and published reports covering very similar territory to that explored by the US National Academy of Medicine. Technical issues, such as safety and effectiveness seem more likely to raise the same issues across nations than they will to vary. For each national bioethics commission to examine the science separately seems a wasted effort.

However, this does not so obviously follow in relation to normative questions of acceptability. I have argued that it is insufficient to see the creation of bioethics governance as a response to moral disagreement – the problem of pluralism – although that is undoubtedly an aspect of the conditions that make it necessary. There is certainly disagreement across the globe about these recent advances. These disagreements are to be worked through in a way that avoids the trap of relativism. Some ways of resolving disagreements are entirely compatible with the relativist idea that all ethical positions should be regarded equally – Oregon's introduction of assisted dying legislation after a narrow plebiscite told us nothing about the quality of arguments, only the distribution of opinion on them. Like the UK's judicial interventions it is (from a bioethical perspective) and amoral mechanism for resolving the disagreement.

Bioethics commissions may bring to the international stage resources to ensure that the philosophical substance of issues is debated and explored rather than conflict managed and dissolved through diplomacy. At Nuffield, we are working on two specific questions that suggest that this is an important set of questions.

- I. The 'rule' that germ-line gene therapies are inconsistent with human dignity as protected in the UNESCO Declaration.
- II. The rule – this time a very concrete one enshrined in legislation in the UK – that research on human embryos should cease before the end of the fourteenth day after the process of the creation of the embryo began.

If these rules stay in place they will constrain scientific research that we have reasons to think might be fruitful, although of course there are no guarantees and we should not hype them beyond this limited claim.

We have a challenge as a community of national ethics committees to find a way for the exploration of these issues to address normative issues. We need to work out whether there are sound moral arguments behind the current positions or whether they were no

more than a consensus formulation that enabled the debate to be deferred to a future time – that is now.

The UK legislation explicitly links the 14 day rule with the appearance of the ‘primitive streak’. The Warnock report, on which the legislation is based refers to this as an appropriate way of meeting the need for a ‘precise decision’ (para 11.19) to allay public anxiety because it ‘marks the beginning of individual development’ (para 11.22). Elsewhere in the report reference is made to the ability to feel pain (para 11.20), early neural development, and implantation (para 11.21). These are essentially scientific arguments. Only the ability to feel pain is explicitly connected to normative philosophical argument, in the guise of ‘the strictly utilitarian view’ (para 11.20). If this is about science, then we should be able to combine our global resources to ensure the best available evidence, appropriately challenged, is available to support bioethical diplomacy.

However, the U.K. experience may be more plausibly characterized as a compromise than a philosophical argument. The nature of the deliberative process was that the outcome was agreed but no consensus was necessary on the reasons. Thus, the 14 day rule made its way onto the statute book as a compromise amongst Parliamentarians and has endured because it remained broadly acceptable to the interested publics and scientists. A similar story might be told about the UNESCO declaration, which has been the subject of academic critique and debate, but has endured as a document around which bioethics debate can revolve. It could be said to be philosophically problematic but practically useful.

In the global order, we need to face up to the nettle of the question of whether bioethics is a matter for harmonization or differentiation. I sometimes ask myself, and audiences, whether the UK should be considered as a rogue bioethics state – it has no formal national ethics committee and it has not signed the European bioethics document, the Oviedo Convention. However, we take bioethics governance very seriously. I hope that this brief presentation shows that the Nuffield Council plays a role that is sufficiently similar to that of the Presidential Commission to make comparison interesting. I hope also that you will find fruitful the idea that I have sketched out that an effective national bioethics commission needs to display some distinctive virtues – independence, courage, inclusiveness, openness, and a particular type of practical wisdom that is pragmatic but has integrity.

Thank You!

Jonathan Montgomery
Professor of Health Care Law, University College London
Jonathan.Montgomery@ucl.ac.uk

Chair, Nuffield Council on Bioethics
Chair, Health Research Authority
Formerly, Chair Human Genetics Commission

