

DISCUSSION: ETHICS OF ETHICS COMMITTEES

The ethics of ethical expertise in science, medicine and healthcare policies

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With the global spread of medical and scientific developments such as genetically modified crops, stem cell research and assisted reproductive technologies (ART), many countries have seen another trend, namely the implementation of institutionalised expert advice and expert committees. Ethics committees are becoming a widely used tool in policy making concerning science and healthcare, and expert advice is as common nowadays as it is diverse. The spectrum of experts ranges from physicians, scientists and lawyers to philosophers and social scientists. They act as advisers in local, national, or even transnational ethics committees such as at the World Health Organization (WHO), or at the United Nations Educational, Scientific and Cultural Organization (UNESCO).

However, as recently discussed in the case of the Indian moratorium on genetically modified food plants (such as BT brinjal, a transgenic eggplant resistant to some plant specific pests) (1), the role of these ethics-experts is often far from clear. The question of their practical relevance and democratic legitimacy arises particularly when their democratic role is compared to the role played by media, non-governmental organisations, and direct public consultations. The Indian magazine *Frontline* (2) critically questioned the legitimacy of ethics committees with respect to their relationship with democratically elected policy makers. Thus one may ask about the legitimacy of such ethics committees as they have sprung up of late in the political arenas of both India and Germany.

Democratic science policy between “scientification” and “ethicisation”

In this special collection of articles in the *Indian Journal of Medical Ethics*, therefore, we would like to address the complex relationship between science and democracy, an issue that has been widely discussed in political theory (3-7) but less so in bioethics. The relationship between science and democracy is problematic for the following reasons:

1. On the one hand, democratic politics has to rely on scientific findings as facts, as they are believed to stand aloof from biases and vested interests. On the other hand, theorists of science in the vein of Max Weber, Thomas Kuhn and Paul Feyerabend have cautioned against scientific experts, as they are not always able to steer clear of, or make explicit, the normative presuppositions that may colour their work from the production of facts to the level of theories and conclusions.

If ethical expertise is to be effective and morally and ethically justified, it seems important to better understand the role given to experts in the complex interface of science and democratic politics.

2. Ethical inquiry as a reflective approach to common practices in science requires a critical questioning of the appropriateness of scientific methods, aims and even points of departure. This critical reflection also encompasses the increasing number, globally, of ethical guidelines generated by ethics committees with the participation of ethicists and various other experts. In the context of this “scientification” of political discourse, the question arises: under what circumstances can the liberal democratic state be allowed, on the basis of scientific ethics advice, to interfere with the liberty of citizens to make use of the opportunities offered to them by modern science and medicine? Also, when may the state legitimately interfere with the academic freedom of researchers to chart out their own research agendas?

As Ernesto Laclau has pointed out, there is a general trend towards “ethicisation” of politics. Several scholars have suggested this term to describe the phenomenon of the institutionalisation of ethics advice in science governance. In science, as well as in medicine, we can observe a number of such institutions growing at different levels: at the local level (ethics committees in hospitals or universities), at the meso level (ethics committees in research associations), at the macro level (national ethics councils), and even at the supra-national level (ethics boards hosted by agencies such as WHO or UNESCO). The collection of articles in this issue of *IJME* will problematise this phenomenon of “ethicisation” of politics in connection with the discussion of ethics review boards on all four levels.

The role of scientific experts in modern society

From a very broad perspective it seems that the domain of science and that of society (and politics) belong to two clearly distinct spheres. Whereas science is preoccupied with the unchangeable laws of nature, society in general and politics in particular mark the domain of human agency. Science thus limits the domain of politics by delineating the sphere of things that politics has to accept as a given fact. Science thus defines the domain of those things over which there can be no rational (political) disagreement. Having said this, a possible source of misuse of science in politics becomes apparent, and it is here

that the problem of ethical expertise in liberal democratic societies arises. A scholarly or political discourse can obscure from view a possible domain of collective responsibility and political agency simply by declaring something as a scientific fact, i.e. as universally true, natural and unchanging. This has been a common discursive trick ever since the Enlightenment period where rules legitimising the polity were represented by scholars as if they were laws of nature. Familiar terms such as "natural law," the "state of nature" (from where to derive the legal-ethical principles that govern society) and "natural rights" come to mind. If the rules governing society are based on natural laws then politics is bound by them. Thus, by way of representing certain legal, social, economic or historical phenomena as governed by "laws of nature," the world of science assumes precedence over the world of politics. Policies can be represented as necessary if they can be portrayed as in congruence with some alleged natural law. In this way, modernity has been represented as a process driven by "natural laws." The same is true for "secularisation," "progress" and "globalisation." In actual fact, however, there is nothing necessary or law-bound about these historical processes. They may continue in the perceived direction but they may also stall, or reverse, depending on contingent factors. But if they are represented as if they were natural processes, they can no longer be the object of human agency and have therefore to be taken into account by state and politics, no matter what. After all, politics as human agency cannot change the laws of nature. Medicine and healthcare as policy fields are particularly pertinent here.

Thus, it turns out that what is presented as natural, universal and unchanging is often cultural, contingent and subject to historical change. The latter would normally be the domain of history or social sciences. However, even the social sciences have at times fallen prey to a positivist (Comptean) attitude that treats the domain of the social on a par with the domain of nature. Here again the Enlightenment acted as a "godfather." Notably, Immanuel Kant distinguished between the domain of human agency and free will on one hand and the domain of natural law on the other. He did not take into account the domain of the cultural or the social as a separate category. In this category, rules do obtain but these rules are not hard and fast, like natural laws, but open to change by collective actors. It is this domain of collective agency that is the province of ethics. Norms govern society by way of generic rules. But in contrast to natural laws, these generic rules allow for exceptions. They have to be interpreted and applied by individual human beings, which leads to variation and change over time. Norms that govern society are part of a socially shared convention that transcends the individual human being. Thus they cannot be changed at will by individual actors alone. They are represented as rules that society imposes on the individual. From the perspective of the collective, however, and from a political point of view, these rules are open to change.

Keeping this in mind, science and scientific experts (with science we hereby refer to all disciplines, not only natural sciences) have a particular responsibility not to lend themselves

too easily to the legitimising role that science can play in political discourse.

As institutionalised sources of legitimacy, experts play a central role in modern society. As sociologist John W. Meyer (8) has pointed out, their authority derives not from their strength as actors but from their ability to assimilate and develop the rationalised and universalistic knowledge that makes action and actor-hood possible. This authority is organised in academic institutions. As disciplines they are devoted to specific bodies of knowledge and their dissemination. Their rationalised knowledge structure constitutes the superego of modern society, replacing in good measure the older religious frameworks.

The advantages of scientific and ethical advisers to policy makers and law makers may not easily be dismissed. They may be in a position to detect social and ethical problems at an early stage and they may function as an internal self-control mechanism of society as they try to integrate expertise from different fields - not only ethics, but also the pure and applied sciences and the social sciences. However, one has to keep in mind that representing social rules as natural laws serves to limit the political debate over them. By doing so, scientists can play into the hands of those who do not like to be questioned about or held responsible for the social, legal and political norms that they generate or enact.

Thus misconceived, the role of experts runs the risk of becoming the equivalent of a new priestly caste from which statesmen, legislators and policy makers derive their legitimacy. The high priests of modernity, however, are also common citizens of their own respective polity and as such they have a share in the burden of collective responsibility. As various ethicists have argued, "ethical expertise" may not always be equated with "moral expertise." We have summarised and argued this elsewhere (6, 7). What is needed, however, is an ethics of expertise, or an ethics that takes into account the socio-political justification as well as the professional ethos of experts in ethics committees.

Practical function of ethics boards in science and healthcare policies

One way to analyse and understand these issues in the relationship between the social system of science and society at large is to analyse the changing role of the "authority" of experts over the leading paradigms, methods and practical consequences of their expertise. Their analysis of the role of expertise offers a model for a better understanding of the relationship between science, society, and politics. Expertise and scientific advice in policy making take very different shapes: At least seven functions can be observed:

1. Advice to legislators and executive organs;
2. Information or training of policy makers with regard to state-of-the-art science;
3. Facilitating compromise and consensus between conflicting interest groups;

4. Initiating and moderating public discourse;
5. Simulating public deliberation based on broad information;
6. Developing concrete guidelines and recommendations; and
7. Monitoring materials and arguments used by policy makers.

Each of these functions may be meaningful and justified. However, what is often missing when a board is set up is a systematic and transparent justification of the functions assigned to it. Therefore what is needed is a discussion of the benefits and burdens of the political-philosophical role of expertise in modern, democratic societies and a discussion of the processes of their legitimisation at the intersection between bioethics, political theory and social science.

To illustrate what could be meant by "ethicisation" of expert advice, Germany can serve as a case in point. In various respects, Germany offers a good example of an "expertocrat" model of science and healthcare politics. For several legislative periods two national ethics committees existed, one with Parliament (Bundestag), the other set up by the Federal Chancellor (Bundeskanzler) to advise the government. Both were in many ways competing with each other and struggling with regard to their legitimisation and political influence (Bogner and Menz have done an exemplary analysis of this [9]). Furthermore, there are several committees assigned to national bodies and societies (for stem cell research, for the allocation of public healthcare, for the ethics of organ transplantation, for end-of-life decisions, for bio-safety, for gene therapy, for genetic testing, etc.). In addition to these national level boards, more than 50 ethics research committees or institutional review boards were established at regional levels (about 10 for living organ donation in different parts of Germany). Clinical ethics committees that deliberate in local conflicts are quite rare compared with the US where about 90 per cent of all hospitals have such institutions. However, more interestingly, in contrast to neighbouring countries like Switzerland, the Netherlands, Great Britain, or Denmark, in Germany, the involvement of the broader public (through mechanisms such as citizens' conferences, focus groups and round tables) is still rare. In India, the above-mentioned case of public deliberation on BT brinjal points in the same direction.

With the papers included in this publication, we can identify four different, but related, topics in future bioethics that seem worth elaborating from different angles. These are: 1) the normative justification of expertise within the broader framework of democratic deliberation; 2) the epistemic justification of expertise; 3) the critical assessment of expertise within the global system of academic exchange; and 4) the existing power relations within society and the relationship between experts and non-experts. From these four perspectives the following questions arose and were addressed by the contributing authors:

1. A question pertaining to the normative justification of expertise within the broader framework of democratic deliberation is: what kind of ethical criteria do we have to attribute to expert work, and what consequences should experts face in the event that these criteria are not met? *Erica Blom and Raymond de Vries* show in their discussion of genetic research among Native American populations in the 1990s that lack of cultural sensitivity among researchers can lead to failure on ethical or even legal grounds. In their critical analysis of this case, Blom and de Vries show that neither the ethics committee's work nor existing ethical guidelines sufficiently reflected the cultural sensitivity of the research. Nor did they sufficiently address the issue of ethical misconduct by researchers. To increase cultural sensitivity as well as to detect ethically critical issues for researchers, the authors argue for a direct dialogue between the researchers, ethics committees and populations involved.
2. A question pertaining to the epistemic justification of expertise is: what makes expert knowledge superior to other forms of knowledge? As the paper by *Yordanka Krastev* illustrates, referring to the development of ethics committee work in Bulgaria, the political climate as well as international influences are important factors that determine what is regarded as "expert knowledge". Recent international developments have led to the insight that experts need specialised training in ethics in order to be able to fulfil their role. The paper of *Pratibha Nadig, Medha Joshi and Aradhana Uthappa* provides insights into current work and the background knowledge of Indian ethical review boards. The results of their quantitative survey show that sufficient knowledge of ethics and legal requirements by the experts cannot always be presupposed, but a third of the ethical review boards are conducting internal audits to ensure the quality of their procedures.
3. A question pertaining to the critical assessment of expertise within the global system of academic exchange is: how should we deal with "battles of expertise", with expert dilemmas and issues of uncertainty and ignorance? In their paper, *Marie-Charlotte Bouësseau, Andreas Reis and W Calvin Ho* advocate an intensified international exchange between national ethics committees to reach a broader consensus. They argue that international organisations such as the WHO should assume a leading role in moderating and consensus-building in this domain.
4. A question pertaining to the existing power relations within society and the relationship between experts and non-experts is: how will the process of expertise do justice to the perspectives of both patients and the broader public? Without this we could be running the risk of a polarisation along the lines of populism on one hand and "expertocracy" on the other. Using the case of Israel, *Carmel Shalev and Yael Hashiloni-Dolev* show in their paper that technocracy in bioethics leads to a decentralised governance system in which legal experts and medical professionals can decide over life and death without involving the patient

community or the broader public. This system sponsors a kind of paternalism that is at odds with liberal democratic precepts of individual autonomy and inclusive democratic deliberation.

The concept of the "autonomy of science from the social institutions that legitimated it" may have become (or may have always been) an illusion, as science historian Dhruv Raina has pointed out (10). However, even falling short of complete autonomy, there are many ways in which ethics advice can be kept independent of political and vested interests without depriving the state of its ultimate prerogative to decide on normative issues regulating its social life. This is what the contributions assembled in this special issue make very clear. Thus, the dialogue between researchers, ethics committees and populations should be increased, scientific experts should be awarded special training in ethics before joining ethics committees, inter- and supra-national organisations should be involved in procedures of international moderation and consensus-building, and, finally, decisions over life and death should always be conducted in close dialogue with the community of concerned patients and the broader public. Since social rules, unlike natural laws, involve individual and collective interpretation, adaptation to local contexts, and cultural sensitivity, their enactment and enforcement necessitate a maximum of democratic participation at all levels.

This special collection of articles on the ethics of ethics committees has been guest-edited by Dr Silke Schicktanz and Dr Michael Dusche.

Acknowledgements: *The authors would like to thank the Jawaharlal Nehru Institute for Advanced Studies, New Delhi, for providing research fellowships and support for a workshop on ethical expertise in life science and public health issues, held in Spring 2010 at JNU. This workshop provided an intellectual framework for this special thematic issue. Silke Schicktanz's stay at JNU was funded by the University of Goettingen International Office.*

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Towards local participation in the creation of ethical research guidelines

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Abstract

Research ethics committees are entrusted with implementing guidelines to protect both scientists and human subjects of research from harm. These guidelines are often based on western contexts and may not resonate with the local moral traditions of the communities that they seek to protect. In this essay, we discuss how using principles of deliberative democracy with a "local derivation" approach may help in the drafting and implementation of ethical guidelines for research that better serve society.

The Havasupai Indians of the United States (US) struggle with phenomenally high rates of diabetes. The disease has ravaged

their community and left its members desperate for aid. In the early 1990s, help seemed to arrive when research scientists from the University of Arizona came to the Havasupais' home deep in the Grand Canyon. The researchers offered to provide genetic clues to the tribe's diabetes epidemic in exchange for individual blood samples. Formal ethical procedures related to the project appeared fulfilled: researchers received approval from a research ethics committee (REC), and the participating Havasupai gave their consent. At the time, the partnership between the researchers and the Havasupai seemed unproblematic.

Researchers then used information gained through an analysis of the Havasupais' blood to locate their ancestors far from