



From designer babies to surrogate mothers: The role of ethics experts in regulating biomedicine

In the wake of the scandal over gene-edited babies in China, **Kristian Krieger** and **Nathalie Schiffino** discuss what role official ethics advisory bodies can and should play in regulating biomedicine

Governments and scientists struggle to develop suitable regulatory responses to the rapid advances in biomedical research and technologies. Biomedical advances, in particular interventions into the human reproductive processes, such as human cloning, stem cell research, and post-mortem insemination, raise complex ethical questions.

Two recent headlines underline the challenge. In November 2018, Jiankui He, professor of biophysics at the University of Shenzhen, announced the birth of twins, known by their pseudonyms Lulu and Nana, whose DNA was edited to increase their resistance against being infected with their father's HIV. The response to this news was swift and condemning, especially by scientists working in this field, calling the experiments undertaken irresponsible, unethical, and even monstrous. Critics point to the violation of numerous international and Chinese ethical guidelines by He, including questions about the medical necessity of the intervention, the consent by the parents, and the veil of secrecy under which the experiments were conducted.

A few months earlier, in summer 2018, French President Emmanuel Macron called for a public debate on medically assisted reproduction. While being in favour of such assistance in general, Macron excluded surrogacy, i.e. carrying out a baby for someone else, from his favourable assessment. Macron's ambivalent position highlights value conflicts, here the right to a family or children versus respect for the dignity of the female body, often encountered when governing biomedicine.

As professional self-regulation shows its limits and policy-makers are compelled to get involved in these policy areas characterized by high technical complexity and value ambiguity, recent decades have seen the proliferation of ethical policy advisory bodies set up by governments. Ethical advisory bodies often bring together eminent experts and practitioners from the technical fields in question – along with lawyers, social scientists, philosophers, and experts from other disciplines.

But can ethical expertise really aid political decision-making given that different viewpoints can claim equal credibility? What legitimates such expertise given that it results in unelected experts influencing how decision-makers address

societal value questions and conflicts? To better assess the actual role and influence of such bodies, we take a closer look at Belgium's Advisory Committee on Bioethics (BACB) and its work on assisted reproductive technologies (ARTs).

Biomedicine and its regulation in Belgium

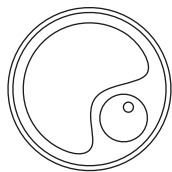
Belgium's medical services are among the leading providers of ART treatments in Europe. The country has one of the highest per capita numbers of treatment cycles and has become a major recipient country of patients from other countries seeking treatment.

This leading position of Belgium's providers of ART has been facilitated by the state's permissive regulatory stance towards the treatments. In fact, for a long time, governments in Belgium relied on self-regulation by the medical professions. However, between 2003 and 2009, the Belgian government introduced a comprehensive regulatory framework, covering a broad range of issues such as reproductive cloning, use of embryos for research, post-mortem dissemination, and gamete donations. Intriguingly, even though Belgium had its fair share of controversy over reproduction (as a constitutional crisis over liberalising the abortion law in the 1990s showed), the debate and adoption of the regulatory framework concerned with ART remained publicly largely uncontested.

Ethical expertise in Belgium's biomedicine regulation

As the legislation was discussed, policy-makers were able to draw on opinions by Belgium's Advisory Council on Bioethics (BACB – Comité consultatif de Bioéthique de Belgique). The BACB was set up as an advisory body to the government and parliament as early as 1993. It has, since then, produced more than 70 opinions, 22 of which were concerned with ART issues, and it established itself as the leading expert body in bioethics in Belgium.

The proliferation of opinions – in most cases following the request of Belgium's policy-makers – demonstrates that ethical expertise exists and is in fact systematically sought by governments. The opinions themselves provide statistical, juridical, and ethical arguments and facts before delivering concrete recommendations to policy-makers. What is notable is that



BACB opinions, including those directly related to ART legislation, include different options and viewpoints within a single opinion.

This diversity of viewpoints represented in the opinions affects the BACB's impact on policy-making. Direct influence on legislation is limited and selective, necessarily weighting some viewpoints and options over others. A case in point is surrogacy motherhood. Several attempts have been made to regulate the practice but to no avail. The corresponding opinion by the BACB is complex, reflecting divergent perspectives on several aspects of surrogacy motherhood, such as the relationship and contract between the surrogate mother and the parents or managing potential risks of commercial exploitation. Opinions including diverse positions fail to provide policy-makers with clear-cut guidance to aid decision-making.

While the ethics experts' direct influence is thus limited, it is important to take into account other pathways through which experts can play an important role in developing policies. Different positions found within the opinions are frequently used by Belgium's parliamentarians to clarify their own positions in debates, anticipate conflicts, and develop compromises. In other words, the diversity in views allows Belgian parliamentarians to use expertise strategically in the policy-making process. Moreover, being composed of ethical and legal experts, as well as medical practitioners, the BACB acts as a relay between practitioners and legislators in developing and implementing regulation. Notably, the BACB promoted the idea of requiring 'conventions' (a form of contract) as a prerequisite for treatments. Specifically, conventions define terms of an agreement between the treatment supplying centre and the patient, for instance, about the destination of the frozen gametes or the rights and duties of the parties linked by surrogacy motherhood. Conventions have been in use by ART centres in Belgium – the BACB's promotion ensured that the practice received recognition as a legal and procedural concept at the federal level.

Influence and embeddedness of ethics bodies

The specific pattern of influence of Belgium's ethics council is interesting for a number of reasons. The limited direct influ-

ence mitigates concerns about the undue influence of unelected experts on questions about life and death. Ethics councils – even if they concentrate knowledge-based authority – remain advisory bodies, not decision-making bodies. This purely advisory role is also reflected in the fact that President Macron launched a public debate even though the French equivalent to the BACB, the Comité Consultatif National d'Ethique, had provided its opinions already.

The indirect forms of influence, in particular the politico-strategic use of BACB opinions by Belgium's policy-makers, tell us another story. Belgium's political system is characterized by deeply institutionalized cleavages, most notably the one between secular and faith-based pillars. This leads to political strategies among the groups and parties associated with the different pillars to avoid inter-pillar conflicts and seek political compromises.

The form the BACB has taken, its interventions, and the pattern of influence, echo the specific needs and constraints of this system. The experts gathered in this body are chosen to represent the secular and religious pillars of Belgian society. By reflecting different positions within opinions (in contrast to, for example, the French council which delivers consensus opinions), they enable a well-reasoned debate with a view to facilitate cross-pillar compromises among politicians. Moreover, conceptual and procedural innovations by the council's experts, as in the case of conventions, can often be accommodated more easily than singular positions in contested fields such as biomedical regulation.

Outlook

As biomedicine advances ever more rapidly and medical self-regulation struggles to keep up, governments need to engage with complex morality policies where technical complexity meets value debates. Faced with these challenges, governments turn to ethics experts. These experts can provide important insights by revealing and clarifying value conflicts and possible arguments. In spite of the scientific and ethical authority of experts, fears of an 'expertocracy' seem unwarranted as the case of the BACB shows that advisory bodies are embedded and thus institutionally constrained in Belgium's

political systems. However, this context dependence of the role of experts also points to the need to analyse how expert bodies work in other countries and to what extent they assume there a more entrepreneurial and influential role.

REFERENCE

Further reading: Schiffino, N. and Krieger, K. (2018) 'Advisory bodies and morality policies: does ethical expertise matter?' *Policy Sciences*, <https://doi.org/10.1007/s11077-018-9338-0>

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