COMMENTARY

# "CRISPR babies": What does this mean for science and Canada?

Bartha Maria Knoppers JD PhD, Erika Kleiderman LLB BSc

■ Cite as: *CMAJ* 2019 January 28;191:E91-2. doi: 10.1503/cmaj.181657

The response to the announcement in China on Nov. 25, 2018, of the "first clustered regularly interspaced short palindromic repeats [CRISPR] babies"[1] is reminiscent of that surrounding the 1978 birth by in vitro fertilization of Louise Brown, the "first test-tube baby." Will this new form of gene editing, of genetic enhancement, of germline modification, or even better, of "gene surgery" — as it was labelled by its creators, Dr. He and colleagues — eventually become equally commonplace?

CRISPR gene-editing techniques are not new. But ethicists and scientists around the world seem to have uniformly condemned the experiment. The genetic alteration of the 2 embryos that were implanted and carried successfully to term was reported to make the children resistant to possible future HIV infection. The health of the babies, the success of the editing or, indeed, the "gene surgery" itself were not scientifically validated or peer reviewed.

The universal ethical condemnation of this experiment bears examination, as do the implications for gene-editing research generally and for policy guidance and laws in the field. The ethical critiques can be grouped into 4 common themes: eugenics, risks to children, failure of self-regulation and the "chilling effect" on scientific research.

The spectre of eugenics is a common, historical leitmotif surrounding genetic "innovations." While often considered to be a rote response, such discourses serve to remind us of the need to discuss proposed genetic interventions prospectively. For example, are these interventions aimed at serious, untreatable conditions, or are they merely intended for the purposes of enhancement (the latter being generally proscribed)?[2] In the recently reported Chinese case, gene editing was used for couples in which the male partner was HIV positive and the female was unaffected. HIV transmission can generally be prevented by sperm washing before in vitro fertilization.

This ties in with the second theme: that of risks to future children and parental freedoms. Today, recourse to in vitro fertilization in the situation of infertility or serious genetic conditions is a recognized medical treatment. In this situation, however, embryos were altered (apparently unsuccessfully in 1 of the children) to avoid the transmission of HIV to them and their future offspring. In that sense, the personal, reproductive autonomy and desires of the parents for biologically related offspring was the driver above considerations of possible health risks to their children. There was no scientific validation of the possible off-target effects and safety of the technique used. There are also no laws or policy that grant access to in vitro fertilization solely for "biological relatedness" in the absence of infertility or genetic indications.

**KEY POINTS**

- Ethical critiques of the announcement of recent advances in gene editing can be grouped into 4 broad categories: concern about eugenics, considerations about the health risks to children, allegations of the failure of professional self-regulation, and concern about a "chilling effect" on scientific research.
- Basic research using germline modification should be permitted if scientific standards are followed for preclinical evidence and accuracy.
- Our current hybrid model of statutory law plus codes of ethics for the governance of emerging biotechnologies is insufficient; it should be complemented by models based on a human rights approach.

Those who claim a failure of professional self-regulation assume a lack of professional codes of conduct, which is a false assumption. The failure here is not an absence of self-regulatory mechanisms but of implementation of China's own laws and guidelines, which were not adhered to by He and colleagues.[3] The international ethics community has opined on the subject of gene editing and, in particular, germline modification since the beginning of the Human Genome Project in the 1990s.[4] Like human reproductive cloning, human germline modification of embryos that are then implanted is not currently permitted. Certain countries, such as China, do, however, allow research on embryos before 14 days, if not implanted.[5]

In contrast, the "chilling effect" critique — that is, the fear expressed that legitimate progress will be stifled — is real. According to Francis Collins, "[s]hould such epic scientific misadventures proceed, a technology with enormous promise for prevention and treatment of disease will be overshadowed by justifiable public outrage, fear and disgust."[6] Fortunately, the closing statement of the Second International Summit on Human Genome Editing in Hong Kong (at which Dr. He explained his "gene surgery"), like other recent guidance, did not call for a

cessation of human germline modification for research purposes.[7–9] It left the road open for a translational pathway for germline editing research, as long as scientific standards were followed for preclinical evidence and accuracy.[7]

In Canada, the 2004 *Assisted Human Reproduction Act* prohibits both the research and clinical applications of human germline modification. Under section 5(1)(f) of the criminal law, it prohibits any alteration of "the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants." Any contravention leads to both a fine and possible imprisonment, or both (s. 60). Yet, criminal bans are generally not considered appropriate mechanisms for governing science, as they often lack the necessary flexibility and nuance to adjust to evolving technologies.[10,11] Moreover, criminal law tends to stifle any debate that addresses emerging socio-ethical and scientific issues, to say nothing of basic research.[10]

Perhaps the time has come to reorient our models of governance of emerging biotechnologies from reliance on the hybrid model of statutory law plus codes of ethics. Gene-editing research holds much promise for individuals, families and communities at risk for serious genetic conditions. More importantly, article 27 of the 1948 *Universal Declaration of Human Rights* gives "[E]very one the right […] to share in scientific advancement and its benefits." This right has been signed and ratified by 169 countries, including Canada, under the 1966 *International Covenant on Economic, Social and Cultural Rights*. It includes not only the freedom of science and the right to access its benefits, but also the right to research. As a human right, it is legally actionable against national governments such as Canada.[12] It contains the potential for a balanced consideration of the issues, above the fray of personal "morality" arguments.

Human rights are universal and create positive obligations. Canada's criminal prohibition of basic research using human germline modification is unnecessarily restrictive. We need a renewed Canadian conversation. A novel human rights approach would, as Juengst put it, "reorient our conversation from policing science to governing society and would shift our focus from avoiding risks to protecting opportunities."[13]

## References


1. Kolata G, Wee S-L, Belluck P. Chinese scientist claims to use CRISPR to make first genetically edited babies. *The New York Times* 2018 Nov. 26.
2. So D, Kleiderman E, Touré SB, et al. Disease resistance and the definition of genetic enhancement. *Front Genet* 2017;8:40.
3. Zhang D, Lie RK. Ethical issues in human germline gene editing: a perspective from China. *Monash Bioethics Review* 2018;28:1-3.
4. Isasi R, Kleiderman E, Knoppers BM. Genetic technology regulation. Editing policy to fit the genome? *Science* 2016;351:337-9.
5. Song L, Isasi R. The regulation of human germline genome modification in the People's Republic of China. In: Boggio A, Almqvist J, Romano CPR, editors. *Human germline genome modification and the right to science: a comparative study of national laws and policies*. Cambridge (UK): Cambridge University Press. In press.
6. Kolata G, Belluck P. Why are scientists so upset about the first CRISPR babies? *The New York Times* 2018 Dec. 5.
7. Baltimore D, Charo A, Daley GQ, et al. On Human Genome Editing II: statement by the Organizing Committee of the Second International Summit on Human Genome Editing. Washington (DC): The National Academies of Sciences, Engineering, and Medicine; 2018. Available: http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11282018b (accessed 2018 Nov. 29).
8. National Academies of Sciences, Engineering, and Medicine. Human genome editing: science, ethics, and governance. Washington (DC): The National Academies Press; 2017:328 p.
9. *Genome editing and human reproduction: social and ethical issues*. London (UK): Nuffield Council on Bioethics; 2018.
10. Knoppers BM, Isasi R, Caulfield T, et al. Human gene editing: revisiting Canadian policy. *NPJ Regen Med* 2017;2:3.
11. Kleiderman E. The regulation of human germline genome modification in Canada. In: Boggio A, Almqvist J, Romano CPR, editors. *Human germline genome modification and the right to science: a comparative study of national laws and policies*. Cambridge (UK): Cambridge University Press. In press.
12. Chapman A, Wyndham J. A human right to science. *Science* 2013;340:1291.
13. Juengst ET. Crowdsourcing the moral limits of human gene editing? *Hastings Cent Rep* 2017;47:15-23.


**Competing interests:** None declared.

This article was solicited and has not been peer reviewed.

**Affiliation:** Centre of Genomics and Policy, McGill University, Montréal, Que.

**Contributors:** Both authors contributed to the conception and design of the work, drafted the manuscript, revised it critically for important intellectual content, gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

**Correspondence to:** Bartha Knoppers, bartha.knoppers@mcgill.ca