EMBO reports

Opinion

The Council of Europe should not reaffirm the ban on germline genome editing in humans

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In reaction to recent progress in human embryo genome editing, the Council of Europe is resolutely on its way to reaffirming a 20-year-old policy banning all inheritable interventions involving the human genome. This approach, which was well justified two decades ago, is now outdated, overly restrictive and will hamper promising research for germline gene therapy. A ban no longer makes sense from an ethical point of view.

Until recently, there has been a worldwide consensus among scientists and policymakers not to modify the human germline. The main rationale was that classical genetic engineering technologies in humans were inefficient and imprecise. The risks were simply too great. But the risk assessment was based on recombinant DNA technology, which is much less precise than the new genome editing technologies—with the flagship CRISPR/Cas9 system—that are much more efficient and precise. Although they are not yet sufficiently safe to be used in clinical trials, research has made rapid progress in improving efficiency and precision of the CRISPR technology [1]. With further improvements, gene-editing technology therefore has the potential for safely modifying the human germline for prophylactic and therapeutic purposes.

There were also concerns about misusing germline engineering for eugenic ends. However, the ethical case for developing a safe option for eliminating inheritable gene defects has gained wide consensus as shown by the widespread use of embryo biopsies in ART to select against hereditary diseases and the recent approval of mitochondrial replacement therapy in the UK. For some, genetic engineering in fact provides a more ethical option as it does not involve the destruction of embryos when it is done on germ cells or stem-cell precursors of germ cells. While it is true that genome editing of the germline would benefit only a small subset of patients when PGD with embryo selection is not an option (e.g. if one parent has two copies of a dominant mutation), there is no convincing reason not to permit research in these areas. Even if eugenic applications such as gene enhancements should remain off-limits, it is unethical to hold hostage patients with severe genetic diseases to fears of a distant dystopian future.

The fear of premature and risky use of therapeutic genome editing is behind a report of the Council of Europe's Committee on Social Affairs, Health and Sustainable Development on the use of new genetic technologies in human beings [2]. The forthcoming Parliamentary Assembly of the Council of Europe on October 9–13 is scheduled to debate the document [http://assembly.coe.int/nw/xml/XRef/Xref-XML2HTML-en.asp?fileid=23791&lang=en#tabs-session-35]. The report suggests that the Assembly recommend to the Committee of Ministers a five-step plan including fostering a broad and informed public debate on new genetic technologies, the development of clear national positions on the use of genome editing, instructing the Council of Europe Committee on Bioethics to assess ethical and legal challenges and developing a common regulatory and legal framework.

But the by far most important step is to urge EU member states, which have not yet done so, to ratify the Convention on Human Rights and Biomedicine—generally known as the Oviedo Convention—without further delay or, at a minimum, to put in place a national ban on establishing a pregnancy with germline cells or human embryos after genome editing.

The Council of Europe's 1997 Oviedo Convention is not only the first, but still the only legally binding international treaty in bioethics. Article 13 bans any interventions in the human germline, either in embryos or germ cells. While it allows modifying the genome of human somatic cells for preventive, diagnostic and treatment purposes, it prohibits any modification of germline genes, whether for therapeutic or non-therapeutic aims. And while the Oviedo Convention allows research on human embryos *in vitro,* it prohibits the creation of human embryos for research (Article 18.2). Therefore, the recent experiments reporting genome editing of human embryos in the USA to erase a heritable disease are not allowed by the Oviedo Convention.

Of the 47 member states of the Council of Europe, 29 states have signed and ratified Oviedo, six states (including Italy, Sweden and the Ukraine) signed it, but have not ratified it, and 12 states (including the UK, Germany, Austria and Russia) have not signed it at all. The Netherlands, which had already signed it, recently decided not to ratify it, because of the limits the Oviedo Convention puts on embryo research.

The policy of reaffirming an absolute ban on any interventions into the human

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DOI 10.15252/embr.201745246 | Published online 6 October 2017

germline is in sharp contrast with recent international developments. The report on human genome editing (NASEM2017) from an international committee convened by the US National Academy of Sciences and the National Academy of Medicine gives a "yellow light" to clinical trials using heritable germline genome editing, if they are undertaken within an effective regulatory framework. On the occasion of the 20th anniversary of the Oviedo Convention, an international conference will be held on 24–25 October 2017 by the Council of Europe [http://www.coe.int/en/web/bioethics/20th-anniversary-of-the-oviedo-convention], which would be an excellent opportunity to discuss not reaffirming an outdated ban but updating the Oviedo Convention to recognize, permit and regulate new techniques to allow safe human germline genome editing for therapeutic and preventive aims.

Conflict of interest

The authors declare that they have no conflict of interest.

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