

One Year After Hong Kong Summit, Developments in Human Genome Editing Underscore Urgency for International Agreement on Standards and Oversight

By Molly Galvin (mailto:mgalvin@nas.edu) | Dec. 4, 2019

It has been a little over a year since the Second International Summit on Human Genome Editing (https://www.nationalacademies.org/gene-editing/2nd_summit/) in Hong Kong,

where scientist He Jiankui (pictured above) announced the birth of twins whose healthy embryonic genomes had been edited to confer resistance to HIV. The revelation drew condemnation from the summit organizers and much of the international scientific community.

Many institutions — including the U.S. National Academy of Sciences, the U.S. National Academy of Medicine, and the Royal Society of the U.K (which co-hosted the summit with the Hong Kong Academy of Sciences) and the World Health Organization — have stated that any clinical use of heritable human genome editing, which allows genetic alterations to be passed onto future generations, would be irresponsible at this time.

The announcement in Hong Kong served as a wake-up call to the scientific and medical communities that more needs to be done to reach international agreement upon requirements that should be met before heritable genome editing could be deemed permissible. To that end, the U.S. Academies and the Royal Society — with the participation of science and medical academies around the world — formed the International Commission on the Clinical Use of Human Germline Genome Editing (https://nationalacademies.org/gene-editing/international-commission/index.htm). The commission has been tasked with developing a framework that will identify a number of technical, scientific, medical, and ethical requirements that should be considered by researchers and policymakers for any potential clinical application of heritable human genome editing. In addition, the WHO appointed an expert committee to form global standards for governance and oversight of human genome editing.

Even since these efforts began, other developments only continue to stress the urgent need for the commission's work. The science of genome editing is moving ahead rapidly, and recently, Russian researcher Denis Rebrikov told *Nature* (https://www.nature.com/articles/d41586-019-03018-0) that he is editing a gene linked to deafness in humans and is awaiting regulatory approval to implant edited embryos to establish a pregnancy. The Russian health ministry has said (https://www.statnews.com/2019/10/16/russia-health-ministry-calls-human-embryo-editing-premature/) that clinical use of human germline editing would be "premature."

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"Since the first international summit in Washington, D.C., in 2015, our Academies and the Royal Society have taken leadership on initiating and continuing a crucial global dialogue

on the responsible use of human genome editing," said National Academy of Medicine President Victor J. Dzau. "We convened this commission because so much is happening so quickly, especially in regard to human germline editing. Policymakers, the scientific and medical communities, and the public need timely, thoughtful, and deliberate guidance on these issues."

Expected in the late spring of 2020, the commission's report — in tandem with the work of the WHO's expert committee — will help inform the development of sound regulation and oversight around germline editing. The report's proposed framework could serve as a basis for the formation of a potential pathway from germline genome editing research to clinical use, if society concludes that heritable human genome editing applications are acceptable. Most recently, the commission held a public workshop in London on Nov. 14-15, one of several information-gathering efforts, including a series of webinars, a public call for evidence, and an Aug. 13 public meeting in Washington, D.C. Archived video and more information can be found on the commission's web page

(https://nationalacademies.org/gene-editing/international-commission/index.htm). The National Academies of Sciences, Engineering, and Medicine

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