On November 26, 2018, media around the world reported that a Chinese scientist had claimed twin girls were born in China from embryos he had genetically edited. There is still doubt about the claim, since no scientific evidence supporting his claim has been provided.

The genome editing technology allegedly used enables alterations at arbitrary locations on a gene. The scientist decided to modify a gene in a manner that would prevent the transmission of HIV to the children from the HIV-positive father. However, parent-to-child transmissions of HIV can be avoided through existing reproductive technologies including *in vitro* fertilization and Cesarean sections. Thus, there was no medical necessity to edit the targeted gene.

At present, the use of genome editing in human fertilized eggs is premature for the following two reasons. First, the technique used has not been proven safe in humans, meaning unforeseen health problems for the gene-edited twins are possible. Second, unlike the genome editing of human somatic cells, by gene editing the embryo, effects could be passed to the children's offspring.

In addition to these technical points, there are also problems from the perspective of research ethics. It has been reported, for example, that the informed consent process may have been inadequate, such that the parents were not properly informed when they agreed to participate in the study. It has also been reported that the scientist may not have obtained formal approval from the Institutional Review Board of his institution for the experiments. Moreover, Chinese regulations prohibit the implantation of a gene-edited fertilized human egg into a living creature. If the scientist did indeed ignore any of these research ethics procedures, then he risks compromising public trust to himself, the field and all scientific research.

The International Society for Stem Cell Research (ISSCR) and the National Academies of Sciences, Engineering, and Medicine (NASEM), which have previously discussed ethical issues related to genome editing technology and produced related policies and reports, have indicated that genome editing in human fertilized eggs should be limited to basic research and that great discretion is needed for the clinical application of this technology in human reproduction (see the <u>ISSCR</u> and <u>NASEM</u> statements). In Japan, the Science Council of Japan and the Expert Panel on Bioethics (Cabinet Office) have also discussed conditions for the genome editing of human fertilized eggs and adopted a position that any clinical applications should be prohibited for the time being. Also, the United Nations Education, Scientific and Cultural Organization (UNESCO) has issued an emergency statement in response to this matter, in which it asserts opposition to the clinical application of this technology at present and demanded all governments, research institutions, and individual researchers conduct research activities following globally accepted ethical principles (see <u>UNESCO</u> statement).

Based on the above, we believe that the implantation of gene-edited fertilized eggs into humans should be prohibited at present. Other ethical issues related to genome editing also require further examination (see Genome editing of human embryos Parts 1 and 2). Under current circumstances, the scientific community, medical practitioners, governments, patient groups and the general public are encouraged to continue discussing the clinical applications of gene editing fertilized human eggs. We will initiate research that will contribute to the discussions.

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