First Human Embryo Gene Editing Done in US

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July 27, 2017

Human embryo gene editing has been performed for the first time in the United States, according to the communications department at Oregon Health and Science University (OHSU).

Shoukhrat Mitalipov, PhD, head of OHSU's' Center for Embryonic Cell and Gene Therapy, and colleagues used CRISPR-Cas9 technology, which allows scientists to edit genes with unprecedented precision, to potentially fix defective genes that cause inherited diseases, according to *MIT Technology Review,* which first reported the research.

The embryos were allowed to develop only for a few days.

The peer-reviewed study is expected to be published next week in a yet-unnamed scientific journal, according to OHSU's communications department, which declined further comment until publication.

Until now, only three such experiments have been published — all by scientists in China. The first two showed poor results, and the third was more promising but used only six embryos, according to media reports. Dr Mitalipov's team reportedly used "many tens" of embryos.

In November last year in the journal *Nature* , Carl June, MD, who specializes in immunotherapy at the University of Pennsylvania in Philadelphia, was quoted as saying after the technology was used in China, "I think this is going to trigger 'Sputnik 2.0,' a biomedical duel on progress between China and the United States, which is important since competition usually improves the end product."

Last year, James Clapper, US Director of National Intelligence, in a report to the intelligence community, counted gene editing among threats posed by "weapons of mass destruction and proliferation."

Some critics have bitterly opposed what they say will become attempts to create "designer babies."

However, the National Academies of Science, Engineering, and Medicine said earlier this year in a report that "the technology is advancing very rapidly…making heritable genome editing of early embryos, eggs, sperm, or precursor cells in the foreseeable future 'a realistic possibility that deserves serious consideration.' "

"A Wake-up Call"

Marcy Darnovsky, PhD, executive director of the Center for Genetics and Society in Berkeley, California, said the research should not have been done and called the upcoming findings "a wake-up call."

"Unlike dozens of other countries, we don't have legislation in place that prohibits using edited human embryos to initiate a pregnancy," she said.

Use of edited embryos for that purpose would have to be approved by the US Food and Drug Administration (FDA), and consideration of such an application by the FDA is currently prohibited.

"But there's no codified legal prohibition and those are in place in more than 40 other countries," she said.

The question this new research considers is monumental, Dr Darnovsky said, and could lead to new ways to discriminate. It needs to be addressed by nationwide deliberation, not a single research team, she added. "There's no moral authority for a decision of this magnitude."

"This is not a door that can be opened just a crack," she told *Medscape Medical News*, adding that she would argue it's not a door that should be opened at all.

She adds that such research is not necessary.

"We already have embryo screening techniques for that exact purpose and they would be effective in the vast majority of cases."

Morally Appropriate

Janet Malek, PhD, associate professor in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas, takes a different view.

She says there are many situations in which this technology is morally appropriate to use."The cases in which it is most appropriate to use are when it's used to eliminate a serious, debilitating disease," she told *Medscape Medical News*."There are some risks with it, but also potential benefits and in cases where the diseases are serious, debilitating diseases, the benefits pretty clearly outweigh the risks."

As for embryo screening, Dr Malek said, "that includes creating a lot of embryos and discarding the ones we don't want, whereas this technique, in theory, would allow correction of a genetic disorder within a particular embryo, so the ethical issues of that are actually pretty dramatically different."

"You're picking who exists rather than benefiting somebody."

Drs Darnovsky and Malek report no relevant financial relationships.

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Cite this article: First Human Embryo Gene Editing Done in US - *Medscape* - Jul 27, 2017.