What are the Ethical Concerns of Genome Editing?

Most of the ethical discussions related to genome editing center around human germline because editing changes made in the germline would be passed down to future generations.

Overview

The debate about genome editing is not a new one but has regained attention following the discovery that CRISPR has the potential to make such editing more accurate and even "easy" in comparison to older technologies.

Bioethicists and researchers generally believe that human genome editing for reproductive purposes should not be attempted at this time, but that studies that would make gene therapy safe and effective should continue.[1] [2] Most stakeholders agree that it is important to have continuing public deliberation and debate to allow the public to decide whether or not germline editing should be permissible. As of 2014, there were about 40 countries that discouraged or banned research on germline editing, including 15 nations in Western Europe, because of ethical and safety concerns.[3] There is also an international effort led by the US, UK, and China to harmonize regulation of the application of genome editing technologies. This effort officially launched in December 2015 with the International Summit on Human Gene Editing in Washington, DC. For more information on this summit, see What's happening right now?

NHGRI uses the term "genome editing" to describe techniques used to modify DNA in the genome. Other groups also use the term "gene editing." In general, these terms are used interchangeably.

Ethical Considerations

Safety

Due to the possibility of off-target effects (edits in the wrong place) and mosaicism (when some cells carry the edit but others do not), safety is of primary concern. Researchers and ethicists who have written and spoken about genome editing, such as those present at the International Summit on Human Gene Editing, generally agree that until germline genome editing is deemed safe through research, it should not be used for clinical reproductive purposes; the risk cannot be justified by the potential benefit. Some researchers argue that there may never be a time when genome editing in embryos will offer a benefit greater than that of existing technologies, such as preimplantation genetic diagnosis (PGD) and in-vitro fertilization (IVF).[4]

However, scientists and bioethicists acknowledge that in some cases, germline editing can address needs not met by PGD. This includes when both prospective parents are homozygous for a disease-causing variant (they both have two copies of the variant, so all of their children would

be expected to have the disease); cases of polygenic disorders, which are influenced by more than one gene; and for families who object to some elements of the PGD process.[5] [6],

Some researchers and bioethicists are concerned that any genome editing, even for therapeutic uses, will start us on a slippery slope to using it for non-therapeutic and enhancement purposes, which many view as controversial. Others argue that genome editing, once proved safe and effective, should be allowed to cure genetic disease (and indeed, that it is a moral imperative).[6] They believe that concerns about enhancement should be managed through policy and regulation.

Lastly, commenters on the issue are concerned that the use of genome editing for reproductive purposes will be regulated differently inside and outside of the U.S., leading to uses considered objectionable to the American public. These arguments cite the largely self-regulated environments of the reproductive clinics that offer PGD and IVF[7],[8] and the existing differences in regulations among different countries.[9]

Informed Consent

Some people worry that it is impossible to obtain informed consent for germline therapy because the patients affected by the edits are the embryo and future generations. The counterargument is that parents already make many decisions that affect their future children, including similarly complicated decisions such as PGD with IVF. Researchers and bioethicists also worry about the possibility of obtaining truly informed consent from prospective parents as long as the risks of germline therapy are unknown.[10]

Justice and Equity

As with many new technologies, there is concern that genome editing will only be accessible to the wealthy and will increase existing disparities in access to health care and other interventions. Some worry that taken to its extreme, germline editing could create classes of individuals defined by the quality of their engineered genome.

Genome-Editing Research Involving Embryos

Many people have moral and religious objections to the use of human embryos for research. Federal funds cannot be used for any research that creates or destroys embryos. In addition, NIH does not fund any use of gene editing in human embryos. (See: U.S. and NIH regulations and perspective)

While NIH will not fund gene editing in human embryos at this time, many bioethical and research groups believe that research using gene editing in embryos is important for myriad reasons, including to address scientific questions about human biology, as long as it is not used for reproductive purposes at this time.[11],[12] Some countries have already allowed genome-editing research on nonviable embryos (those that could not result in a live birth), and others have approved genome-editing research studies with viable embryos.[13],[14] In general, research that is conducted in embryos could use viable or nonviable embryos leftover from IVF, or embryos created expressly for research. Each case has its own moral considerations.

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