

Safe and ethical ways to edit the human genome

February 27 2017, by Rosa Castro



Credit: AI-generated image ([disclaimer](#))

The National Academies of Science and Medicine (NASEM) released a [report](#) on Feb. 14 exploring the implications of new technologies that can alter the genome of living organisms, including humans.

Although scientists have been able to edit genes for several decades, new

genome editing technologies are more efficient, more precise and far less expensive than previous ones. One of these techniques, known as CRISPR-Cas9, could allow for new applications ranging from editing viruses and bacteria to animals, plants and human beings.

For example, scientists could design [pest-resistant plants](#). They could modify the genome of animals, bacteria and [viruses](#) to help fight diseases and plagues.

CRISPR could potentially be used by [almost anybody](#) willing to tinker with the genome. This, and the fact that it can be used either for beneficial or harmful purposes, have raised fears that CRISPR could become a [weapon of mass destruction](#).

CRISPR could also be used to modify the [human genome](#). The big question scientists are wrestling with is whether these technologies should be used to make modifications in human reproductive cells. Changes made in these cells are heritable from one generation to the next, and are called germline modifications.

Some scientists working with these techniques called for a [moratorium](#) for editing that could result in germline modifications. Others thought that a [prudent path](#) for using these technologies was needed.

The NASEM report did not endorse a moratorium. But it recommended that at least [10 stringent conditions](#) should be met before authorizing this use. The report also said that more discussion – with wide public participation – was needed before proceeding with human germline modification.

I explore the ethical and policy questions raised by emerging technologies such as CRISPR at the [Duke Initiative for Science and Society](#). I am particularly interested in how different countries regulate

these technologies.

What does the report say?

For research using human cells and tissues, the [NASEM Committee](#) said that existing regulatory and ethical frameworks were able to address the questions that might arise from genome editing. The same is true for genome editing of cells in the body that are not reproductive cells –called somatic cells – for therapeutic purposes.

So while clinical trials for modifications of somatic cells were given a green light, the modification of [reproductive cells](#) (eggs, sperm and embryos) which would lead to germline modifications, was given a [yellow light](#) for the moment.

These types of genome modifications have raised fears about a [brave new world](#) of "designer babies."

These questions are not new. The difference is that scientists are closer than ever to actually being able to significantly and accurately [alter the human genome](#).

Recommendations for germline modification

The NASEM report concluded that it would be fine to proceed with the modification of [germline cells](#) only if three requirements are met.

One is that further research should prove that there are sufficient prospective benefits relative to the risks of using these techniques before starting clinical trials.

Another is that the public should be involved in a broad dialogue about

the use of these technologies.

And a sound regulatory and oversight framework should be in place to guarantee that the following [10 conditions](#) are met before using genome editing to alter sperm, eggs or embryos:

1. that genome editing is used only when no other "reasonable alternatives" exist;
2. that it is only used to prevent a "serious disease or condition";
3. that use is restricted to altering genes "that have been convincingly demonstrated to cause or strongly predispose to that disease or condition";
4. that use is limited to converting genes into "versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects";
5. that credible preclinical and/or clinical data on both potential risks and potential health benefits of the use of these technologies exist;
6. that the effects of these technologies on the health and safety of the research participant are subject to ongoing and serious oversight during the trial;
7. that a comprehensive plan for "long-term, multigenerational follow-up" that respects personal autonomy exists;
8. that a balance is achieved between ensuring maximum transparency and respecting patient privacy;
9. that both health and societal benefits and risks are continuously reassessed, including through the input provided by the public;
10. and that reliable oversight is put in place to prevent the use of these technologies for reasons going beyond the prevention of a "serious disease or condition."

Most of these conditions aim at ensuring that germline genome editing will be used only to prevent a serious disease, where no reasonable

alternatives exist, and under strong supervision. Some of them will be very difficult to meet. For instance, how can the long term follow-up of children (and their children) born with the help of genome editing be guaranteed? This would be specially difficult with people traveling to other countries to access these technologies.

Finally, the use of [genome editing](#) for enhancement purposes was given a red light for the moment and should be subject to further and wider discussions.

Genome modification in a globalized world

The NASEM report cited [Louis Pasteur](#) – a French microbiologist famous for his many discoveries, including the process of pasteurization – who once said "science has no homeland, because knowledge is the heritage of humanity." The report and the human gene editing [initiative](#) from the National Academy of Sciences and the National Academy of Medicine are paying special attention to international considerations.

An open question is whether the recommendations about human germline editing, which has been interpreted by some as an [endorsement](#) of the practice, are a good starting point for a wide international dialogue.

A [2014 study](#) found that 29 out of 39 surveyed countries have decided to ban the use of technologies to modify the human germline. Of these, countries such as Austria, Italy, Spain and the Netherlands have a ban in place. And others such as Argentina, Greece, Peru and South Africa have ambiguous regulations.

Other genetic modification techniques have been used to conceive babies free of genetic diseases carried by their parents. One such technique, mitochondrial replacement therapy, has recently been used in

[China](#), [Mexico](#) and [Ukraine](#) and will probably be used in the [U.K. soon](#).

However, in the U.S., a rider included in a [Congressional Appropriations Act](#) in place until April 2017 forbids the FDA from considering any trials that will alter the human germline. Experience with [other riders](#) shows that this ban could be extended indefinitely.

The report sought to develop "a framework based on fundamental, underlying principles that may be adapted and adopted by any nation." But how could this framework be adopted by nations that currently ban any germline modification?

In a globalized world, patients can potentially cross borders for medical interventions that are not available in their own countries. This has already happened with [mitochondrial replacement therapy](#). Some countries might decide [to relax their standards](#) in the hope of attracting "tourist" patients or boosting their research capabilities. An international agreement to regulate these technologies would help to set a minimum set of standards that countries should comply with.

But it is unlikely that countries will reach any agreement in the near future. The report noted that different regulatory approaches could be tested in different countries until we better understand these technologies and the best way to regulate them.

Regardless of whether one believes that an international agreement is needed or feasible, international cooperation and dialogue seem to be essential components of good governance for new technologies.

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