

Five principles that should guide future DNA 'editing' in South Africa

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In recent years there have been several major innovations in genetics. One prominent example is [Crispr-Cas9](#), a novel biotechnology derived from bacteria that could be used to make precise changes to specific locations in the human genome - our DNA.



Any man-made changes to the human genome must be carefully regulated. Billion Photos/Shutterstock

Scientists could use Crispr-Cas9 and similar technologies to eliminate genetic diseases by using germline cells (gametes and embryos). This is known as germline editing; a child born from modified gametes or embryos will have such “edits” in their DNA and can pass those on to their future offspring. Of course, as with anything that relates to altering DNA, [controversy abounds](#).

It is possible that germline editing will be ready for public use in the next decade. Currently, however, many [countries lack rules on the use of this technology](#). Therefore, it has been argued that this situation should be rectified to ensure that germline editing is governed by proper legal and ethical rules, although what these rules should be is heavily disputed.

In a [recent paper](#) published by the South African Journal of Science, we investigated the current regulatory framework for germline editing in South Africa. Quite simply, it is lacking and several gaps must be filled. We propose five principles that could guide a proper ethical and legal framework for this and similar technologies.

The status quo

There is a distinction between the rules relating to germline editing by scientists for the purpose of research, and germline editing for use in practice by the general public, known as clinical application.

South Africa's regulatory environment that covers questions of ethics in medicine currently seems to not permit research on, and the clinical application of, human germline editing. This is according to ethics guidelines published by the [Health Professions Council of South Africa](#) and the [South African Medical Research Council](#) – although the justifications for this are unclear.

By contrast, the South African legal regulatory environment allows a regulatory path that would, in principle, permit research on human germline editing. This is because none of the current regulation on research using germline cells prohibits research for the purpose of germline editing. The legal regulation of the clinical application of human germline editing, on the other hand, is uncertain.

When it comes to research, there is currently no South African law that specifically regulates germline editing. It's expected to comply with the same laws and ethical requirements as [all scientific research relating to human reproduction](#). This gap needs to be addressed through new regulations.

When it comes to germline editing as a clinical application, new regulations are required. But the wording will need to be nuanced because germline editing has long term, multi-generational effects that must be taken into account.

The new regulation will also have to manage gaps such as the fact that the practice is viewed under existing regulations as a hybrid of medicine and medical device.

Crucially, germline editing can only proceed if South African law doesn't prohibit it. Some may argue that section 57 of the [National Health Act](#), which forbids the "reproductive cloning of a human being", applies here – and so, they would suggest, germline editing is actually illegal.

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But we disagree with this line of argument. This provision was intended for the purpose of regulating cloning, and because germline editing is different from cloning, this section should not be interpreted as applying to germline editing.

Having considered all this, we propose that five guiding principles should steer future regulation of germline editing in South Africa.

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[*Human gene editing: who decides the rules?*](#)

Principles

Principle 1: Human germline editing should be regulated, not banned.

Human germline editing for clinical application has the potential to improve people's lives. It could, for instance, be used to prevent diseases. For this reason, it shouldn't be ignored or banned; instead proper regulation that considers the potential long-term implications must be considered.

Principle 2: Use the well-established standard of safety and efficacy.

Human germline editing clinical applications should only be made accessible to the public if they are proven to be safe and effective, including for future generations. This will mean that human clinical trials will have to be carried out. These are [challenging, but possible](#).

Principle 3: Non-therapeutic uses of germline editing may be permissible.

Even among those who are in favour of germline editing, it is often claimed that such use should be limited exclusively to the 'therapeutic' in the form of preventing genetic diseases. This, [it is said](#), makes it different from genetic 'enhancement' in the form of germline edits that are not done for the purpose of healing people, but benefiting them. An example of genetic enhancement would be an edit which made a child have a high IQ or greater athletic ability.

These are often viewed as morally reprehensible because they [are reminiscent of the state-sponsored eugenics programmes](#) of early 20th century Britain, America and Nazi Germany.

It is important to note that state-enforced eugenic regimes used coercive means that violated procreative freedom. But individual uses of germline editing technologies promote procreative freedom by leaving their application up to individual choice.

Principle 4: Respect parents' reproductive autonomy.

The choice to use safe and effective germline editing should be made by individual prospective parents because this choice is part of the parents' right to make decisions concerning reproduction. The freedom to use new reproductive technologies like germline editing is one which falls under the protection of section 12(2)(a) of South Africa's [Constitution](#).

Principle 5: Promote the achievement of equality of access.

New technology may only be accessible to the rich, worsening existing inequalities in society – particularly in societies like South Africa given the wide [gap between the rich and poor](#), and the [lack of access to healthcare](#) for the underprivileged. However, the possibility of inequality cannot be a reason to suppress the technology. Instead it should be a reason for measures to be taken that promote access for the underprivileged.

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