

Human genome editing and the need for regulation and deliberation

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Introduction

Since 2012, with the initial publication of the CRISPR-Cas9 system [1], a new biotechnological tool is available that makes genome editing easier and faster, more precise and less cost-intensive compared to other genome-modifying tools. This novel biotechnological tool holds great promise for new therapeutic approaches in germline modification to treat or even cure genetic disorders and diseases. However, in 2015, with first rumors about a study conducted by a group of Chinese scientists who applied the CRISPR-Cas9 system in nonviable, trippronuclear human zygotes [2], a debate about the morality of gene editing in the human germline was sparked.

In this debate different moral concerns have been raised which focus on risk and safety issues, the accessibility to the technology and justice concerns, the impact on future generations and the consent of these future generations, as well as fears about human enhancement or so-called “new eugenics” [3]. These concerns are well-known from other debates in bioethics and are based on fundamental values such as dignity, autonomy, justice, beneficence, non-maleficence, and truthfulness. With the rise of the ethical debate there has been an increasing demand for regulating the technique. This demand came partly from the scientific community itself to ensure that responsible research with the CRISPR-Cas9 system can be carried out and that gene editing in humans is safe enough for therapeutic applications and will not be misused for unethical purposes [4, 5]. This viewpoint will discuss possible ways for regulating human genome editing and highlight the limitations of regulation on different levels.¹

Regulation on a global level and the role of scientists

In January 2015, American life scientists as well as experts from bioethics convened in Napa Valley (California) to discuss the medical, legal, and bioethical implications of the CRISPR-Cas9 technique [5]. Scientists

wanted to show that they bear responsibility for the outcome of their research, and that they seek a frank dialogue with experts from other disciplines. In December 2015, the Napa meeting was followed by the “International Summit on Human Gene Editing” held in Washington, D.C. [6]. The Washington Summit – including follow-up meetings and the final report – initiated a process of consensus building amongst worldwide scientists and other experts; this process can be viewed as the starting point for regulating and governing human genome editing.

Scientists play a crucial role in that process because they have the best insights into the research on CRISPR-Cas9. In this respect, the Napa meeting was a fruitful first step for self-regulating scientific research. Self-regulation can be a quick and effective way for governing emerging biotechnologies like CRISPR-Cas9 which are not on the political agenda yet [7]. The scientific community has its own instruments for implementing guidelines for research and applications as well for sanctioning violations of these guidelines, e.g. by rejecting articles or conference talks that are not in line with a certain code of conduct, by implementing certain funding policies, or by establishing ethical committees at universities to evaluate research.

Self-regulation within the scientific community needs to be complemented by the inclusion of experts from ethics and other disciplines such as law or social sciences [8]: scientists are experts on safety and risk concerns, but they do not have the expertise on normative issues dealing with values like dignity, autonomy, or justice. These ethical and societal values need to be addressed and critically discussed among additional experts from different disciplines to educate scientists and to reach a minimal consensus. The self-regulatory process has to take place on a global level to be as effective as possible: if there is no minimal consensus among the global scientific community, a few scientists might carry out research that will have a negative impact on the overall reputation of science and create distrust among the public.

A scientific self-regulatory approach has its limitations as it lacks democratic legitimation from the public. However, self-regulation can be a fruitful starting point for political discussions on a global level, framed by international bodies like the United Nations, the UNESCO, or the WHO [7]. Ideally, these bodies – because they have the political legitimation – should be the re-

¹ This viewpoint is based on a model of self-regulation published elsewhere together with Nikola Biller-Andorno and Anna Deplazes Zemp [see 7]. I like to thank Anna Deplazes Zemp for helpful comments on a previous version of this viewpoint and for critical discussions on developing the model of self-regulation.

sponsible stakeholders for reaching an international consensus on human genome editing – resulting in a binding convention or declaration. As long as it is possible to develop a political regulation which is binding for all nations, this should be the method of choice. As experience shows, negotiations on the global political level are very time-consuming and do not often lead to a consensus that is accepted by all nations [9]. In this respect, a self-regulatory approach led by scientists might be more effective. However, once there is a sound political concept for an international regulation of human genome editing, it will eventually replace the self-regulatory framework of science [7].

Regulation on a national level and the role of the public

A minimal consensus reached on the global level obviously cannot reflect the various ethical, societal, and cultural views found worldwide. What we need is a pluralistic regulatory approach: specific regulations and legislations on the national political level would be an important complement to a regulation on the global level. The general public should be the central stakeholder in the process of reaching a democratically legitimate consensus [7]. Public participation implies an open, deliberative discussion on whether and – if so – to what extent new techniques like CRISPR-Cas9 should be applied. Beside the public, stakeholders such as governmental authorities and non-governmental organizations should be involved in the deliberative process. National regulations and legislations have the advantage that they reflect the specific societal, religious, cultural, and ethical values and traditions of a certain society. The deliberative process of reaching a consensus for national regulations has to include – similar to the global level – the participation of scientists and experts from ethics and law. Ideally, they should contribute to a well-informed and transparent public debate [8]: scientists offer their expertise on the technology – including the assessment of risks and benefits – whereas ethicists and legal scholars provide the ethical analysis of controversial issues. Thus the role of scientists and additional experts is to ensure a democratically legitimate process of policymaking by educating the public. The public, in turn, is an equal partner in this process by defining the fundamental values which determine the living together and which drive societal development – which, in consequence, also determines the direction of scientific research.

Being part of the process of policymaking is one role that the public can play in the governance of genome editing. In recent years there has also been a debate on how the public can be directly addressed in the process of research: the model of RRI (“responsible research and innovation”) has gained traction especially in the field of emerging biotechnologies [10]. The RRI model

is distinctive from other technology assessments because it stresses direct public participation for defining the purpose of science [10]. Taking the RRI model seriously would mean that even if there is no regulation of genome editing in a certain (democratic) country, the public will have a say in defining the direction of biotechnological research through an RRI approach.

As outlined above, a deliberative process for developing regulations on the national level would be ideal. However, deliberation is only likely to happen in a democratic society. There might be countries where authoritarian regimes develop laws which do not reflect the democratic will or which are not in line with a global consensus. In this case, the scientific community can come into play again by sanctioning the misuse of research in these countries through instruments described above, e.g. by rejecting articles or conference talks. The self-regulatory approach or international agreements should also be guiding for regulating research and applications in countries that have no legislation on genome editing yet. Once a country has successfully established a legal framework, it will be binding for all scientists working in the respective country.

Conclusion

Scientists want to take advantage of the great potentials that the CRISPR-Cas9 technique offers in order to treat and cure human diseases and disorders. In other words, scientists bear responsibility for maximizing the benefits for society through research. However, scientists are also confronted with different moral concerns which CRISPR-Cas9 triggers in public, i.e. they also bear responsibility for addressing these ethical and societal public concerns in their research. In this respect, the self-regulatory process initiated by scientists can be seen as a precautionary approach: scientists critically reflect on their own research together with experts from ethics and other disciplines to find ways for regulating human genome editing *before* research continues and therapeutic applications are developed. Public participation and deliberation is paramount on the national level: a democratic approach and a broad stakeholder engagement can lead the way in determining which ethical and societal values ought to be protected in a legal framework on genome editing. However, there are concerns among some scientists and policymakers that public deliberation might be derailed by extreme opinions which could undermine the freedom of research. The public backlash over agricultural biotechnology in Europe is an often cited example. Anyhow, to limit public participation and deliberation would be the wrong answer to this challenge. The experience with agricultural biotechnology also shows that applying a technology without prior deliberation leads to adverse public perception which negatively

affects research and technological progress. To start deliberation as early as possible and to engage the public not only in the regulatory process but also in the research process (RRI model) might be the adequate answer.

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