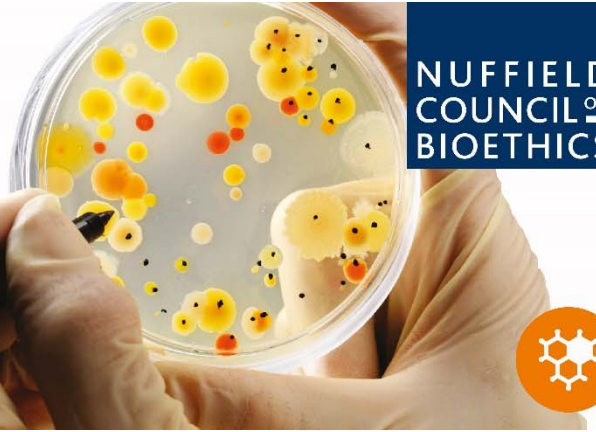


Genome editing:

an ethical review



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Genome editing: *an ethical review* – key points

Recent advances in genome editing such as the CRISPR-Cas9 system have diffused rapidly across almost all fields of biological research. This has raised new expectations and ambitions about human control of the biological world but, at the same time, given rise to a range of ethical questions. In September 2016, the Nuffield Council on Bioethics published an ethical review of genome editing. This initial report will be followed by two further reviews by the Council.

The possible uses of genome editing raise important ethical questions across many areas of application including human health, food production, wildlife and ecosystems, and industrial, military and amateur uses – see below. Because these questions differ depending on the context of application, we believe that simply focussing on the technology itself is not the best way to approach further appraisal of the ethical and social issues. Instead, in the next stage of our work, in which we will develop advice, conclusions and recommendations, we will look at genome editing from the point of view of the challenges and fields of activity on which it is having or is expected to have an impact.

Possible applications of genome editing and associated ethical concerns

Human health

Applications may include:

- Health research using genome edited animal models to study genetic diseases (including ‘personalised’ disease models)
- Treating disease, through cell-based therapies (e.g. treating HIV or leukaemia using genome-edited white blood cells) or gene therapy to correct mutations (e.g. muscular dystrophy)
- Avoiding the inheritance of single gene conditions, e.g. cystic fibrosis and thalassaemias
- Introducing gene variants that confer ‘desirable’ phenotypic traits

Key ethical concerns:

- Concerns about the risks of unintended effects due to off-target DNA alterations
- Concerns about the implications of genome editing in reproductive treatment, for example, making changes that will be passed on to future generations. Issues including outcomes, risks, costs and societal impact have implications for governance and regulation
- Concerns that widespread of genome editing may amount to ‘liberal’ eugenics driven primarily by the choices of parents
- Concerns that potential benefits and harms of genome editing might not be distributed equitably
- Concerns about how to delineate morally acceptable and unacceptable uses of genome editing for governance purposes

Food production

Applications may include:

- Improving the efficiency of development and production of crops for consumption, e.g. speeding up progress of breeding programmes to increase yield, pest resistance and nutritional benefit
- Improving the efficiency of development and production of animals for consumption, improving yield, disease resistance, or making livestock better adapted to conditions of intensive farming or of subsistence agriculture)?

Key ethical concerns:

- There are concerns about food safety and about the welfare of intensively farmed animals
- A key issue is whether or not food produced using genome editing should be classed as 'GM' as this has important consequences for regulation, labelling and public perception

Wildlife and ecosystems

Applications may include:

- The creation and release of genetically altered insect species to control infectious disease or crop pests, e.g. altered mosquitos to halt the spread of malaria and dengue fever

Key ethical concerns:

- There are concerns about the uncontrolled proliferation of gene drives in the wild which may upset fragile ecosystems or have unintended ecological consequences.

Industrial, military and amateur use

Applications may include:

- Industrial applications in bacteria include production of fossil fuel alternatives, antibiotics and vaccines
- Defence interests that may exploit genome editing to counteract biological or chemical aggression
- Amateur applications include the use of the low cost technology by DIY 'garage' scientists

Key ethical concerns:

- Genome-edited organisms (as with all genetically modified organisms) pose a possible risk to those handling them, to others, or to natural ecosystems if they are released or escape from controlled environments
- The possibility of the technology being put to harmful uses, for example in the production of bacteria intended to cause a disease outbreak

Triage of ethical issues and next stages of work

We divided the societal and moral issues into three categories: those that should be addressed urgently, those that may need to be addressed in the near future, and those that should be kept under review. Our prioritisation was based on what we take to be the moral significance of the issue in the current societal and legal context.

Issues that should be addressed urgently are:

- The potential application of genome editing in human reproduction – i.e. intergenerational alterations (e.g. for the purpose of avoiding genetic disease).
- The use of genome editing in livestock (e.g. to improve animal husbandry and food production).

We have now begun an inquiry addressing the ethical and practical questions raised by the potential uses of *genome editing in human reproduction*. Our report on the subject will be published in 2017. In 2018, following a further inquiry, we will publish a report on the uses of *genome editing in livestock*.

Issues that may need to be addressed in the near future are the use of genome editing to control insect populations that spread infectious plant and animal disease, especially in combination with 'gene drive' approaches; and to make animal tissues and cells suitable for transplantation to humans (xenotransplantation).

Issues that should be kept under review include the governance of genome editing to develop new cell-based therapies for existing diseases, and to develop new plant strains in agriculture.

Copies of the report are available from: <http://nuffieldbioethics.org/project/genome-editing/>

To help shape or inform the work of the Nuffield Council on Bioethics please contact: +44 (0)20 7681 9619 or bioethics@nuffieldbioethics.org