

SUMMARY OF REPORT

Genome editing and human reproduction: social and ethical issues

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The Nuffield Council on Bioethics has published the findings of an in-depth inquiry into the ethical issues arising from heritable genome editing interventions in humans. This was one of the areas identified as requiring further ethical scrutiny in our 2016 report, *Genome editing: an ethical review*.

We conclude that the use of heritable genome editing interventions to influence the characteristics of future generations **could be ethically acceptable in some circumstances**, provided:

- it is intended to secure, and is consistent with, the **welfare of a person** who may be born as a consequence of interventions using genome edited cells; and
- it upholds principles of **social justice and solidarity**, i.e. it should not be expected to increase disadvantage, discrimination, or division in society.

UK law currently prohibits genome editing interventions in human reproduction. This should only change after there has been an opportunity for broad and inclusive societal debate and the implementation of robust governance measures guided by the principles set out above.

Recommendations for research bodies

- We recommend that research to establish the clinical safety and feasibility of genome editing should be supported in the public interest in order to inform the development of evidence-based standards for clinical use.
- We recommend that social research that would help to understand the welfare implications for people born following heritable genome editing interventions (for example, involving people born following preimplantation genetic testing) should also be supported in the public interest.

Recommendations for UK Government

- We recommend that, before any move is made to amend UK legislation to permit heritable genome editing interventions there should be sufficient opportunity for a broad and inclusive societal debate.
- We recommend that, without awaiting the opportunity for a thoroughgoing review, the Secretary of State for Health and Social Care should give consideration to bringing within the scope of licensing any heritable genome editing interventions that currently fall outside that scope.
- We recommend that heritable genome editing interventions should be permitted only provided that the impact on those whose vulnerability to adverse effects (including stigmatisation and discrimination) might thereby be increased has been assessed and mitigated (and, in any case, not without open and inclusive consultation with people in those positions).

- We recommend that heritable genome editing interventions should only be permitted provided that arrangements are in place to monitor the effects on those whose interests may be collaterally affected and on society more generally, and that effective mechanisms are in place to redress any such effects; this should include a clear regulatory measure to trigger a moratorium and a sunset provision, requiring review and an affirmative resolution to permit the practice to continue.
- We recommend that consideration should be given to the establishment of a separate body or commission in the UK, independent of Government and independent of existing regulatory agencies, which would have the function of helping to identify and produce an understanding of public interest(s) through promotion of public debate, engagement with publics and monitoring the effects of relevant technological developments on the interests of potentially marginalised subjects and on social norms.

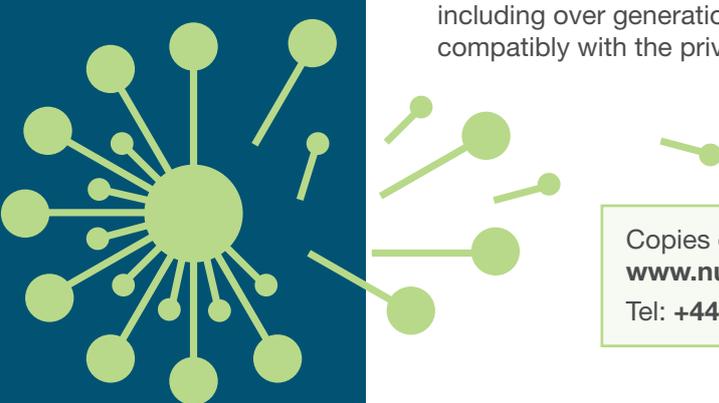
Recommendations for governments in the UK and elsewhere

- We recommend that broad and inclusive societal debate about heritable genome editing interventions should be encouraged and supported without delay.
- We recommend that governments in the UK and elsewhere should monitor and give consideration to the use of intellectual property rights in order to promote the public interest in having safe, effective and ethical heritable genome editing interventions.
- We recommend that the governments in the UK and elsewhere should work with international human rights institutions such as the Council of Europe and UNESCO to promote international dialogue and governance with regard to genome editing research and innovation.
- We recommend that governments in the UK and elsewhere give consideration to bringing forward an international Declaration affirming that people whose genomes have been edited should be entitled to the full enjoyment of human rights.

Recommendations regarding licensing and regulation

If, as a result of legislative review, heritable genome editing interventions are to be permitted, we conclude that they should be subject to strict regulation and oversight by a national competent authority.

- We recommend that genome editing should be licensed for clinical use only once risks of adverse outcomes have been assessed by a national competent authority (in the UK, the Human Fertilisation and Embryology Authority).
- We recommend that heritable genome editing interventions should be licensed, initially, on a case-by-case basis.
- We recommend that heritable genome editing interventions should be introduced only within the context of well-designed and supervised studies, reporting regularly to a national coordinating authority, and that the effect on individuals and society, including over generations, should be closely monitored as far as possible, compatibly with the privacy of the individuals concerned.



Copies of the report are available to download or order from
www.nuffieldbioethics.org

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