Heritable genome editing ‘morally permissible’ but will require ‘international consensus’

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Nuffield Council on Bioethics has found that heritable genome editing could be ‘morally permissible’ but will require significant governance to ensure that genome editing proceeds in an ‘ethically acceptable’ manner. Lawyers from Allen & Overy, Fieldfisher and Mills & Reeve LLP, and academics from Newcastle Law School, discuss the importance of regulation in this ‘ethically difficult, but socially and commercially important field’, highlighting that it is ‘not a decision for the UK government to make unilaterally’.

The Council recommends that two principles should guide the use of genome editing. These are:

• they must be intended to secure and be consistent with the welfare of the future person
• they should not increase disadvantage, discrimination or division in society

Other findings include:

• research should be carried out on the safety and feasibility of genome editing interventions to establish standards for clinical use
• social research should also be carried out, to develop greater understanding of the implications of genome editing for the welfare of the future person
• the UK government should work with international human rights institutions, such as the Council of Europe, to promote international dialogue and to develop a framework for international governance of heritable genome editing intervention

The Council also recommends the establishment of an independent body in the UK to promote societal debate on the issue, and related scientific and medical developments.

‘Only a matter of time before human germline editing becomes a reality’

Isabel Teare, lawyer at Mills & Reeve LLP, notes that the question surrounding ‘designer babies’ has been around for a long time, but the recent emergence of ‘highly accurate gene editing techniques’ means that researchers are now able to ‘manipulate genetic material much more easily’.

Teare adds it is ‘only a matter of time before human germline editing becomes a reality’, due to a ‘powerful desire’ of parents to improve their children’s future lives, as well as ‘economic incentives’ for those developing techniques to tackle genetic diseases.

Dr Ilke Turkmendag, acting director of Law, Innovation, and Society at Newcastle Law School, highlights that the UK’s scientific progress in this field would largely depend on both the ‘optimism of the public, and its reputation for “permissive-but-strict” regulations’.

Turkmendag warns that it is ‘important to critically assess whose voices, and which assumptions shape any future regulations, the worldwide implications of the UK’s regulatory decisions, and our responsibilities toward future generations.’

Laëtitia Bernard, partner at Allen & Overy, says that ‘much of the position in the national law in many countries—including the UK—will need to change before it is legal to perform gene editing of germ line cells or embryos for reproductive purposes’.

Bernard adds: ‘The exclusion from patentability for such processes will also need to be amended before they can be patented. If the status quo of unpatrientability remains, once CRISPR-Cas9 research on animal genomes leads on to research into commercial human interventional products or services, it is likely that any applications for patents will either be refused or opposed on the grounds of being unpatrientable subject matter, well before any issue of enforcement arises.’

Bernard also notes that inventors will likely ‘fully explore other options to secure patent protection’ and ‘push the boundaries of existing case law in this regard’.
‘Likely to raise human rights claims’

Sarah Ellson, partner at Fieldfisher, says it is important that although the Nuffield Council’s recommendation is that genome editing could be ethically applicable does not mean it should be ‘allowed to be done anytime soon in the UK’:

‘Any legislation will take time to develop and debate, the Nuffield report is intended to help inform that debate. Were it to be decided that this is something we want to allow to happen in the UK, it is likely that the law will follow a pattern similar to the tests which already exist, which means that embryos can only be tested for pre-implementation genetic diagnosis for the most serious of diseases or abnormalities.’

Turkmendag discusses the human rights claims that are likely to stem from heritable genome editing, noting that groups such as rare disease patients might push for the ‘right to have a healthy child’:

‘If the regulations allow genome editing to avoid transmission of heritable disease, this would potentially provoke counter-claims from, say disability rights campaigners. These rights claims should be taken into account and given an equal weight in regulatory decisions.

‘International harmonisation through soft law could be a possible solution, as such mechanisms can help establish a universal common goal for genome editing in a domain where the actions of a single country can have global impact.’

‘Not a decision for the UK to make unilaterally’

Professor Dave Archard, chair of the Nuffield Council on Bioethics said: ‘Huge advances are happening in genomics research, and whilst we have to acknowledge that genes alone do not shape a person, the possibility of using genome editing in reproduction to secure or avoid a characteristic in a child offers a radically new approach that is likely to appeal to some prospective parents.

‘There may be good reasons for allowing some parental preferences to be met, but we need to be careful that the use of genome editing to help parents to exercise these preferences doesn’t increase social disadvantage, discrimination or division and that close attention is paid to the welfare of those involved, especially any child born as a result.’

Teare notes that law and regulation in this area ‘varies widely between countries’, but the engagement by Nuffield Council is a ‘welcome development’. Tear adds that that the right approach is to ‘build an international consensus now’, instead of waiting for human germline modification to become a reality.

Bernard adds: ‘While the fact that subject matter may be found unpatentable on the basis of being “contrary to ordre public or morality” (Article 6(1) of the Biotechnology Directive 98/44/EC) allows the law to flex and shift in line with changing societal attitudes, it also leads to inherent uncertainty in the legal position of patents in this ethically difficult, but socially and commercially very important field.

‘Should it eventuate that the germ line gene editing is practically unpatentable, then in the absence of the commercial incentive provided by patents, it may well be the case that public funding will be required for the public interest to gain the most from developments in this technology that are applicable to humans.’

Turkmendag concludes that even if the research can be proven as safe and in the best interest of future children, the UK should not permit heritable genome editing by itself: ‘These techniques will affect the entire human genome pool, and therefore not a decision for the UK government to make unilaterally.’

Source: Report: Genome editing and human reproduction—social and ethical issues