REGenableMED

Submission of comments on

"Genome editing"

Nuffield Council on Bioethics, Open call for evidence

Comments from:

Dr Aurélie Mahalatchimy and Prof Alex Faulkner on behalf of the REGenableMED consortium

Please find below comments on 'Genome editing' by the REGenableMED consortium.

REGenableMED - REGenableMED is a United Kingdom Economic and Social Research Council (ESRC)-funded project (N°ES/L002779/1: http://www.york.ac.uk/satsu/regenablemed/). It brings together research team builds on work by social science experts based in Birmingham, Edinburgh, Sussex and York in the UK. It is coordinated by Pr Andrew Webster, Science and Technology Studies Unit at the University of York, UK. The project aims to examine the dynamics of innovation within the field of regenerative medicine. Using a mixed-methods social science approach, the project will undertake a detailed analysis of the interplay between business models, measures of clinical utility, patterns of regulatory oversight and clinical workflows within healthcare settings. The results of the research will inform strategies aimed at facilitating the responsible development of effective and useful regenerative medicine products and services.

All work packages of the project consider what we call the 'institutional readiness', i. e. the capacity and willingness of key pre-existing organisations and inter-organisational structures to adopt, respond to and utilise novel technologies, such as advanced therapy medicinal products as part of regenerative medicine. One work package led by Prof Alex Faulkner, Centre for Global Health Policy, School of Global Studies, University of Sussex, the UK is dealing with the role of a range of intermediary agencies, patient groups and health insurance companies, in determining what can be called 'healthcare readiness' for the field, that is, how the field aligns with and can be embedded in existing practice and how far changes need to be made. As part of this work a regular survey of regulatory tools (including relevant linked public consultations) that influence the pathways through which the field develops is performed. The draft response has been prepared by Dr Aurélie Mahalatchimy (academic lawyer) with Prof Alex Faulkner and Prof Andrew Webster (sociologists). A discussion between persons interested was then organised and the attached answer circulated to all project participants before submission.

E·S·R·C ECONOMIC & SOCIAL RESEARCH COUNCIL

The REGenableMED consortium is grateful to the Nuffield Council on Bioethics to have been given the opportunity to contribute to this open call for evidence.

COMMENTS

I- PERSPECTIVES ON GENOME MODIFICATION

1) The distinctive significance of genome interventions

- **Is there anything special about the genome that makes intervening in it different from other ways of manipulating nature (e.g. selective breeding of plants or animals)?**

Interventions on genome have been considered specifically as any modification will be passed on descendants. However, many other activities that do not involve interventions on genome are also passed on descendants. What makes genome modification specific is the intrinsic modification of nature. From the legal point of view, the most special is the human genome modification as it could challenge the fundamental rights of the human person as well as the primacy of the human being over the sole interest of society or science.

- **To what extent can the development of genome editing techniques be regarded as distinct from or continuous with existing techniques? In what way are the differences significant?**

On the one hand, genome editing should be regarded as continuous with existing gene therapies techniques. In that context, it does not raise new questions compare to the ones raise from the beginnings of the human genome project and gene therapies.
On the other hand, what makes genomes editing techniques from existing techniques seems to be the technical ease of doing it. Such facility will require a stronger position of the protection of human being if the limits are to be maintained.

2) Science and society

- **What obligations do scientists involved in developing and using genome editing technologies owe to society and what freedoms should society allow to these scientists? Do genome scientists have any special obligations to society that are distinct from those of other scientists?**

Obligations and freedoms of genome scientists are the same as for any other fields of science: to comply with the law and ethics of researches. However, given the sensitive nature of the genome interventions (involving high hopes, hypes

and fears), transparency, discussion, and communication with the society should be encouraged.

- **To what extent is the development of genome editing valuable as a pure research tool, and to what extent is its value dependent on envisaged practical applications?**

- **What obligations do governments have towards society to ensure 'safe' science or otherwise to shape the scientific research and development?**

Main obligations of the governments are transparency, discussion and communication towards and with the different stakeholders, especially the society. It should also maintain as much as possible the balance between access to new innovative treatments that relies on freedom of research and the protection the fundamental rights of the human person and the integrity of the human being.

3) Science, morality and law

- **What conventional moral principles, if any, do genome editing challenge?**

Respect of human dignity and human genome as common heritage of the humanity, freedom of research

- **To what extent can the moral questions raised by genome editing be addressed using existing moral frameworks or approaches?**

It seems all the moral questions raised by genome editing can be addresses using the existing moral frameworks.

- **To what extent are laws and legal frameworks necessary or desirable in seeking to ensure adherence to the moral principles that should inform genome editing?**

- **What other issues do you feel need to be discussed in the context of genome editing? What do you consider to be the issues of greatest moral concern raised by genome editing?**

II- BIOMEDICAL RESEARCH AND HUMAN APPLICATIONS

1) Current research

- **What is the current state of the art in the field? What are the current technical limitations and constraints/ bottlenecks?**

- **What are the main directions of travel? What are the envisaged endpoints/ applications?**

- **What is the rate of travel? What are the expected timescales for realising the envisaged endpoints?**

2) Conditions of research and innovation

- **What are the main 'drivers' and 'obstacles' in relation to envisaged endpoints?**

- **What bearing do international ethical debates and agreements (e.g. high level statements or calls for moratoria) have on the pace or organisation of research?**

- **Who should lead and who should be involved in setting policy for research and human applications of genome editing? Is this significantly different from other kinds of experimental or reproductive medicine?**

Every stakeholders. It should not be different from other kinds of experimental or reproductive medicine.

3) Impacts

- **Have advances in genome editing affected what research is funded, what research strategies are used (e.g. derivation of stem cells) or the comparative development of therapeutic strategies?**

- **What are the significant decisions that need to be taken before therapeutic use of genome editing may be contemplated (for non-heritable and heritable genetic changes) and who should have the responsibility for those decisions?**

Significant decisions should be taken on heritable genetic changes.

- **Are the benefits and costs of treatments that involve genome editing likely to be distributed equitably (or any more or less equitably than existing or alternative treatments)? In what way might genome editing differentially affect the interests of people in vulnerable or marginalised groups?**

- **What other important questions should or might we have asked in this section?**