Response to Nuffield Council on Bioethics' Genome editing and human reproduction: open call for evidence

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During a meeting held in Trento, Italy in March 2017, and organised by the COST Action CHIP ME (IS1303) to discuss about ELSI of genome-editing (see here), many different positions emerged on the possibility to intervene on reproduction and especially on the human embryo. The Nuffield Council on Bioethics report 'Genome editing: an ethical review' and the report by the National Academy of Sciences and National Academy of Medicine 'Human Genome Editing: Science, Ethics and Governance' were commented on and, as expected among a mix of ethicists, scientists and lawyers, many different views and perceptions of the same passages arose. We considered it especially relevant to improve a public debate about these topics and to foster a wider participation in discussion, in order to verify how the different moral opinions, cultural interpretations and social and political views can bring us to different conclusions and to help to build a wider consensus towards future practical applications of these new, promising techniques. An involvement through ICT is a good system to involve people, but consensus conferences can be useful too, at this stage of the discussion. Citizens science invites one to move in this direction in order to transfer knowledge in a more democratic, value-sensitive and sustainable way.

Overall, gene editing should not be regulated autonomously. Rather, some of its potential uses should be regulated under general existing frameworks and by reference to the existing technologies and techniques which it is replacing. Such will be the case whether we are debating reproductive interventions, genetic therapy, interventions without therapeutic aims, or even gene editing of plants and animal populations. In that regard, it can be assumed that blanket bans on some applications of gene editing are inefficient. Theoretical research and experimentation will tend to relocate to more permissive jurisdictions. Most likely, moratoria will open the way to actors with overwhelming market power to eventually step in pressuring for favourable regulations. Moreover, moratoria could be even counterproductive, due to a simple fact. A technology that is so cheap and easy to use cannot be easily monitored. This means that researchers could avoid it quite easily. In such a scenario, the probability of a man-made disaster (accidental or not) is extremely high. And if it happens, we would have to deal with only on the basis of an outdated scientific knowledge. Thus, in terms of risk prevention, moratoria would not be an advisable approach.

Law and Ethics are separate but intersecting normative systems. Transforming moral principles into legal norms is useful to ensure moral conformity. Legal norms have also a pedagogic effect. However, transposing moral principles into law has to be carefully considered and accessed within the framework of fundamental rights. Such is particularly important in areas such as reproductive technologies and genetic interventions were personal autonomy and human dignity may collide. Legal norms may be necessary to prevent and regulate unwanted uses of technology. However, flexibilities are necessary and legal norms should be interpreted by reference to the advances in science.

A Bio-Law framework in international and national legislation is already established, and is based to a wide extent on a notion of human genes as humanity's common heritage. This legal concept and its linkage with human dignity requires further legal consideration and should not be interpreted literally. International texts clearly defend diversity and the fundamental importance of social and cultural elements. It has also been recognized that epigenetic effects are relevant and that the human species have not ceased to evolve. In the context of gene editing, human dignity should not be understood as equivalent to preserving a (legal) fiction of static biological identity. A more useful regulatory framework should focus on drawing balanced boundaries and establishing guidelines for the exercise of autonomous informed personal choices *vis à vis* their wider social implications.

Law and regulations should address ethical considerations. In this sense, reasonable precaution will remain necessary to address uncertainties without tying up normative choices to scientific unknowns. Safety issues of emerging technology for intervention in the human body can be tackled by individual (and collective) *risk versus benefit* assessment, guiding and underlining autonomous and informed decisions. General safety rules concerning testing on human subjects, clinical use of experimental procedures, clinical trials, product safety and environmental protection can adapt to technological progress. In sum, we submit that regulations should be imbued with flexibility while preserving their preventive and precautionary function.

Ethical evaluations of emerging technology, such as gene editing, will increasingly have to address 'dual-use' dilemmas. For this reason, regulatory approaches should focus on specific uses, aims and end results and not on a given technology. This also concurs with the European Academies Science Advisory Council report (2017) 'Genome editing: scientific opportunities, public interests and policy options in the European Union' where they conclude that policy considerations should be based on the potential applications of the technology, rather than on the new technology *itself*. Gene-editing promises a large number of distinct applications, some more controversial than others. Blanket prohibitions and moratoria do not serve the best interests of society. At the current stage, the preferable route rests in specific ethical evaluation at each stage of research and technology use, accompanied by upfront embedding of dedicated research into the ethical, legal and social implications of the underlying bioscience research.

Emerging technology in life science generally creates heated and emotionally charged public debate. In this context, scientific communication should claim a prominent role to counter the danger of widespread misinformation. A high level of transparency and accuracy should guide scientific communication, while simultaneously global-scale responsibility and governance should be fostered by and for every stakeholder. In that respect, we are convinced that interdisciplinary thinking and multi-level stakeholder dialogue is crucial and should increasingly form part of future legislative initiatives and other types of legal development. Given the extremely complex and dense Intellectual Property landscape in gene editing, it will be particularly important to explore novel ways for governing, managing, and sharing protected technology through clearing houses and patent pools. Additional clarification on the functioning and application of the research exemption and strengthening user-generated solutions at the post-grant level will also be instrumental in mitigating the typical limitations on research imposed by patent rights.[1]

We hope you find the above comments useful and we are available to follow up with additional comments and clarifications if you wish.

Yours sincerely,

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[1] These arguments were explored in more detail in Ana Nordberg, Timo Minssen, Sune Holm, Maja Horst, Kell Mortensen and Birger Lindberg Møller, 'Cutting Edges and Weaving Threads in the Gene Editing (Я)evolution: Reconciling scientific progress with Legal, Ethical, & Social concerns' (forthcoming 2017).