Session H1

Genome editing in human reproduction: Society, Ethics and Governance

Chair: Mara Almeida (Centre for Philosophy of Science of the University of Lisbon)

The interest in possible clinical applications of genome-editing technology derives from the possibility of improving human health by treating and preventing disease. One of the potential applications is in the treatment of genetically inherited diseases. In human reproduction genome-editing is considered to have a potential use, avoiding the transmission of heritable genetic conditions by modifying mutations in germline cells (cells that can give rise to a new individual). For example, genome editing could offer, in the future, an alternative approach to preventing the inheritance of diseases such as cystic fibrosis. In the last years, in the US and China, research studies making use of genome-editing technology have been applied to human embryos to correct a specific gene mutation. More recently, a Chinese scientist has claimed to have used genome editing to produce two human babies with the CCR5 gene edited (a receptor through which many strains of HIV infect immune cells) to make them immune to HIV. These developments seem to confirm the need to consider a responsible and transparent regulatory system for research on germline genome-editing. The prospect of using genome-editing as a reproductive technology in the future also raises important questions on its ethical implications, for example on the integrity of the human genome, which are far from being resolved. A key concern is the possible orientation of research towards human enhancement, going beyond disease prevention into the engineering of 'desirable' genetic characteristics. Other concerns include risks of unintended effects due to off-target genome alterations, and the implications of making irreversible changes that will be passed on to future generations.

The session will focus on the development and application of heritable genome editing interventions and key ethical and social considerations raised at individual and collective level, for current and future generations, for the human species. The session aims to provide a broad view on the different perspectives and visions of experts in the field, including their views on the risks and limitations associated with the technology. The session will also consider and explore possible avenues on the governance of the technology developments, and the relevance of public engagement as part of the process. The session will welcome reflections upon themes such as: a) challenges on defining human 'genetic identity'; b) what constitutes a condition 'deserving' genetic modification; c) where to draw the line between treatment and enhancement; and d) processes supporting a broad and inclusive debate with society. For the session the chair will ask for an open call for papers considering a broader range of diverse positions and views, followed by discussion, to promote an open and interdisciplinary debate.

Accelerating and braking factors for the development of gene editing in the human germline. A view from technology assessment

Author: Ingrid Schneider (University of Hamburg)

Utopian as well as dystopian views on germline intervention are similar in that they often assume a seemingly unstoppable development. I would like to contradict this assumption underlying many texts on genome editing. My paper relies on the view that technological development is not deterministic but depends on complex prerequisites, and may have unintended consequences. However, it can be shaped in a democratic way (Mayntz 2016; Werle 2017).

CRISPR-Cas is perceived as enabling rapid, cost-effective, simple, accurate, and efficient genome editing. This scientific assumption may lower the threshold for such genetic interventions and may tempt researchers to premature experiments on human embryos (Hardt 2019; Jenkui 2018). Some factors of the competitive races can develop acceleration forces. Those include: a) technical feasibility; b) scientific reputation races; c) international economic competition; d) patent races; e) lack of professional self-regulatory restriction of researchers. However, there are also counterforces or inhibiting factors and aspects, such as a) unpredictable risks; b) a missing medical indication; c) the necessary IVF and thus a high number of embryos to be produced and selected (Schneider 2017).

My conclusion will relate to some ethical controversies and rationales on genome editing and will reconsider utopias, dystopias, and questions of ethical and social acceptability. Neither the hopes nor the hype of gene editing should blind sober reasoning. The feasibility of "designer babies" would be based on unsustainable and obsolete notions of genetic determinism that need to be critically scrutinized.

Value meets CRISPR: from value regimes of actions-in-context to TA diplomacy

Author: Karen Kastenhofer (Institute of Technology Assessment)

Other than dedicated mission oriented innovations, genome editing has emerged as an ‘enabling technology’, that is, it has been framed as per se value neutral with the sole specification that it enables human actors. Values only get addressed in relation to specific contexts of application, or, more precisely, in relation to specific actions-in-context. The recent debate concerning the alleged genome editing during an in-vitro fertilisation procedure by a Chinese biophysicist features as the most prominent example.

But of course, as any other social context, all contexts-of-action within the socio-spheres of genome editing are value laden. Variations between such contexts do not concern the intrinsic normative dimension of human action and social spheres, variations concern the modes such values are addressed and responded to. Inherent values can be ignored, negated or explicitly addressed; they can be personalized, localized, collectivized and/or institutionalized; condemned or approved of; labelled as alien or familiar; processed or hidden. I will call situations that are defined by such varying characteristics differing ‘value regimes’ for want of a better label (stretching the existing concept of ‘governance regimes’ so as to encompass aspects of culture and community).

In this presentation, I will delineate different contexts of action that relate to genome editing and that come with very different such value regimes. They are all linked by their shared relevance for genome editing as a perceived element of innovation, albeit separated by their diverging institutional, local and thematic contexts. The assessment of a socio-technological innovation then overlaps with an assessment of its value regimes within the social spheres of the related actions-in-context. In consequence, the outcry about the ‘Chinese CRISPR babies’ can be addressed just as much as an outcry about a socio-technological innovation as as an outcry about the value regime related actions are embedded in.

For technology assessment and technology governance, this approach leads to well-known challenges: can we assess a technology, even a socio-technological innovation, per se? How do we deal with assessments of value regimes and governance regimes imbedded in technology assessment? How should we as TA practitioners respond to the cultural-political dimension of public outcries that goes far beyond the refusal of a technology? Is there such a thing as TA diplomacy

comparable to existing cases of science diplomacy? Such questions can be addressed in relation to the international context of the CRISPR babies' case; but they can also be raised in the context of inherent alienations in national contexts, between academics and non-academics, entrepreneurs and naturalists, or different generations of citizens.

A national dialogue on human genome editing

Authors: Jeroen Gouman, Sophie van Baalen, and Petra Verhoef (Rathenau Instituut)

Human genome editing does not only concern the individuals who are directly involved (i.e., scientists, and in the future possibly prospective parents with a heritable disease, their offspring and health care professionals), but future generations and the whole of humanity as well. Regulatory decisions concerning the desirability of genome editing, and the circumstances under which it might be permissible, therefore requires more than an assessment of safety and efficacy. Issues such as the question whether it is permissible and if so, whether a line can and should be drawn between editing for disease prevention and editing for enhancement ask for a deliberative process in which a wide variety of perspectives and arguments are represented. In addition to the involvement of experts, the public needs to be engaged in this process. Talking with people instead of about them is necessary before governments can make political judgements that influence people's lives and the lives of future generations.

In the presentation we will describe the results of our research that is a pivotal part of a collaborative approach to organize a broad public dialogue in the Netherlands. This initiative is financially supported by The Dutch ministry of Health, Welfare and Sports and carried out by a multidisciplinary group of organizations, representing a wide variety of stakeholders and expertise. The overall project lasts from the beginning of 2019 till the end of 2020 and consists of three phases: an initial, investigative and preparatory phase; a second phase in which diverse publics are engaged in dialogues; and a third phase in which the results of the dialogue are analyzed and reported. As such, the different perspectives and underlying arguments within Dutch society regarding heritable genome editing and its consequences for individuals, future generations, society and humanity will be outlined to inform policy makers.

We will specifically present the outcomes of the first phase of the project, in which we have investigated the ethical issues that are at play, which societal groups are (under)represented in the current debates and the arguments that are voiced in various media, reports and statements. These findings, along with the extensive experience of the Rathenau Institute with technology assessment and public engagement, will result in recommendations that will guide the activities and dialogues that will be organized in the second phase of the project. Additionally, we will present a set of techno-moral scenarios derived from the research in the initial phase that can be used to facilitate discussion during these activities. At the end of our presentation, we would like to invite the audience to exchange their experiences with organizing public dialogues on the ethics of emerging science and technologies such as genome editing.