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German Ethics Council's Opinion: Intervening in the Human Germline

Recommendations and decision paths

This Opinion has set itself the task of reconstructing and assessing the main facets and arguments of the complex debate surrounding the ethical evaluation of germline interventions. It seeks to present these arguments in a comprehensible manner and make them accessible to public and international debate. There have been repeated calls for this debate, not least by the German Ethics Council itself. To this end, the main paths on the road to conceivable decisions on basic and preclinical research on the one hand and clinical applications on the other are depicted in a *decision tree*. With this tree it is possible to illustrate at which points decision paths take different forks in the road, i.e. where ethical concepts are interpreted differently and can thus be used to justify differing conclusions about what the next steps should be. An understanding of these main forks in the argumentation helps to throw light on the different possible positions and on the ensuing consequences in a clear and transparent manner.

However, prior to this, a number of conclusions are presented that have been shown to be capable of achieving a consensus in the German Ethics Council. They can be seen as overarching recommendations irrespective of how the possible use of germline interventions is evaluated overall (and, perhaps, controversially).

Overarching conclusions and recommendations

1. The ethical analysis does not lead to any categorical inviolability of the human germline.
2. The assessment of the permissibility of germline interventions should not be reduced to a mere risk and opportunity analysis. Rather, it should be based on the ethical concepts of human dignity, protection of life and integrity, freedom, non-maleficence and beneficence, naturalness, justice, solidarity and responsibility.

3. The prerequisite for permissibility is, in any case, a sufficient degree of safety and efficacy of such interventions.

4. The German Ethics Council calls for an international moratorium on the clinical application of germline interventions in humans, and recommends that the German Bundestag and the Federal Government work towards a binding international agreement, preferably under the aegis of the United Nations.

This moratorium should firstly create a forum for a transparent process of discussion and evaluation of the possible goals of germline interventions in humans to determine in which cases and under what conditions germline interventions are to be classified as expedient and legitimate in future.

Secondly, it should allow time for careful basic and preclinical research, prevent premature application and classify any such application as a serious violation of both good scientific practice and general rules of good human coexistence.

Thirdly, it should create an arena for the elaboration of suitable instruments for international regulation.

The moratorium should undergo transparent regular review.

5. There is likewise agreement within the German Ethics Council that basic research without recourse to human embryos *in vitro* should be promoted with a view to gaining a deeper understanding of the effects of germline interventions in order to improve the level of knowledge about their safety and efficacy. This includes research involving synthetic human entities with embryo-like features provided they do not have embryo status.

6. Furthermore, the German Ethics Council recommends setting up an international agency that would be entrusted with at least two fundamental tasks:

Firstly, it should draw up and establish global scientific and ethical standards for research on and the practice of germline interventions in humans. It should monitor compliance with these standards wherever such research or practice is permissible. The register that is currently being put in place by the World Health Organisation could be one of the necessary foundations for this task.

Secondly, a standing committee should be set up within this agency to address the scientific, medical, ethical, legal, societal and political implications of germline interventions in humans, to set out possible solutions to the problems that arise and, in this way, to make a contribution to transparency and awareness-raising amongst the public at large.

7. This agency must be able to build on a broad national and international debate. The German Ethics Council, therefore, reiterates the demand formulated in its ad hoc recommendation of 29 September 2017 for the promotion of a global societal discourse on germline interventions. All relevant societal groups must be involved in this international exchange on appropriate ethical standards for the assessment of possible future applications. An international conference hosted by the United Nations or the World Health Organisation would send out a welcome signal for its development on the global level, too.

It goes without saying that public debate and awareness-raising must be stepped up in Germany, too. Various tried-and-tested formats of participation should be encouraged.

The exchange of information should be ensured not just by the scientific community but also by public bodies. The German Ethics Council recommends that the Federal Government launch a structured civic discourse.

Decision paths

Although there is consensus within the German Ethics Council on the above-mentioned overarching recommendations, the concrete ethical evaluation of germline interventions may vary and even take on a controversial note, depending on the interpretation of the relevant ethical concepts and the application context.

One and the same ethical concept can be interpreted very differently with regard to individual questions and individual application scenarios. As outlined in the summary above, and discussed in detail in the full version of this Opinion, the spectrum of the underlying arguments is highly detailed and nuanced. Nonetheless, some clear positions can be formulated and depicted as paths in a decision tree. These paths touch on both basic and preclinical research on germline interventions and their clinical application.

The questions (Q) take on a key or course-setting role in the decision-making processes, which means that the direction taken by the next sections of the paths (P) will be determined by whether the answer to them is *yes* or *no*. Each section of these paths leads to further questions and, possibly, to specific consequences (C) that arise from a particular decision¹.

Most of the questions in the decision tree are geared towards whether an action *may* and also whether it *should* be carried out. *May questions* escalate

¹ Courses of action are not formulated with any claim to completeness but are exemplary in nature. For each one key examples are given.

ethical problems, thereby creating clarity and transparency. In some decision-making situations, however, they may conceal important nuances that are only revealed by the answer to the question whether an action which *may* be carried out, i.e. which is not prohibited, *should* also be carried out. Anyone who believes an action to be not only permissible but even necessary will answer this question in the affirmative. Conversely, anyone who does not want an action to be prohibited but nonetheless believes that it *should* not be carried out, will answer *no*, perhaps because there are more suitable alternatives that should be given preference in the weighing up process. Certain *should questions*, which thus go beyond the *may questions* sometimes facilitate a decisive differentiation when it comes to ethical orientation. Where such a distinction is relevant, the text emphasises this below.