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ETHICAL AND GOVERNANCE CHALLENGES RAISED BY HUMAN GENOME EDITING

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RESPONSES TO THE REPORT ON GERMLINE GENOME MODIFICATION FOR PREVENTING HIV

- If the report in the web is true, what Dr. He did is not just somatic nor germline genome modification, but germline genome modification for enhancement. This is a practice with the least degree of ethical justifiability and acceptability.
- It is the most difficult to assess the risk-benefit ratio in enhancement even for medical purpose. So it is very difficult for us to protect the future child. It should not be our priority, and it should not be on our agenda now.
- There is a convenient and practical method to prevent HIV infection, to use genome editing is something like “to shot bird with cannon”.

MY RESPONSES

- **According to our regulations the protocol of clinical trials should be reviewed and approved by IRB. If the report in web is true the IRB of Shenzhen Meihe Hospital is not the institutional review board of South University of Science and Technology nor the institution Dr. He did his genome editing. So the review is invalid.**
- **According to MOH and MOST regulations on assisted reproduction and embryonic stem cell research, the genetically modified embryo is prohibited to be implanted into human or animal reproductive tract. So what Dr. He did violates the relevant regulations.**
- **Germline genome modification by genome editing for prevention or enhancement both will change the gene pool of human species (*homo sapiens*). How could Dr. He and your team change the gene pool of human species without considering the need to consult other part of human species?**

CONCERNS OF GENOME MODIFICATION BY GENOME EDITING

- During the 8th National Conference on Bioethics held in Shanghai on November 16-18, there was a panel discussion on “Will unruly situation of genome editing occur in mainland China?”

CONCERN 1:

- The unruly situation of gene editing will occur such like the unruly situation of unproven and unregulated “stem cell therapy” during the period of 2005-2012:
  - Hundreds of hospitals in collusion with biotech companies;
  - Direct injection of undifferenciated adult stem cells or umbilical stem cells;
  - Tens or even hundreds thousands of patients taken into trap;
  - The fake stem cell therapy might cost patients CNY tens or even hundreds millions *yuan* out of their own pocket which became fat profits for doctors, hospitals and biotech companies.

CONCERN II:

- During the period of 2010-2015 a dozen of the books for teaching medical ethics were published in which the authors claimed that:
- People with genetic defects or the disabled physically or mentally are “劣生” (*liesheng*. inferior), have no value for reproduction, are burdens to the society, their life has no value, so they should be subject to compulsory sterilization.
- If their suggestion would be accepted by the government, there would have been tens millions of people undergoing compulsory sterilization.

HOW WILL THE PATIENTS AND THEIR OFFSPRING WITH UNEDITED GENOME BE TREATED?

- If future doctors or scientists were trained in this way, how can they treat patients with genetic diseases and the disabled physically and mentally?
- If genome editing for treating and preventing diseases would be widely practiced, part of the people with genetic disease or their gamete/embryo would undergo genome editing, they and their offspring would get rid of genetic condition, the other part of the people won't. Would this latter part of the people and their offspring be probably treated as "inferior", having no value as a human being

THE POLICY THAT THE CHINESE GOVERNMENT OPENLY ANNOUNCED

- In 1998, then President Jiang Zemin pointed out in his congratulatory speech to the 11th Asia-Pacific Conference of Rehabilitation International that:
- "There have been people with disabilities since the dawn of time. They have the desire and ability to participate in social life, and **they are the creators of social wealth, and they pay much more efforts than healthy people. They should enjoy all human dignity and rights as able-bodied people. The liberation of the disabled, the group in the most difficulties in the society, is a major symbol of the development of human civilization and social progress.**”

TWO THINGS WE HAVE TO DO

- **Somatic genome modification by genome editing is proved to be safe and efficacious. Next step: Is to prevent offspring from suffering genetic condition a goal worth to pursue for? The estimated number of thalassemia carriers is around 47.48 million in China.**
- **However, we have to do two things before we reach the stage of clinical trials of germline genome modification editing in human gamete or embryo:**
  - **Building an ethical framework (EF) to evaluate the decision-making scientists, physicians and regulators made;**
  - **Making governance arrangements (GA) for applying genome editing in germline genome modification.**

EF1: PRECONDITIONS FOR APPLYING GENOME EDITING IN GERMLINE GENOME MODIFICATION

- Preconditions:
  - Clinical trials before clinical practices
  - Preclinical research before clinical trials, non-human animal research in particular
  - Basic research to improve genome editing techniques
- All these efforts are to ensure a favorable risk-benefit ratio to protect the future child.

EF2 : PROTECTING THE INTERESTS OF FUTURE PARENT

- The purpose of germline genome modification is to give birth to a child without the genetic condition the future parent suffers. It is our moral imperative to protect the interests of the future parent, including:
  - Seriously implementing ethical requirement of informed consent;
  - Whatever the result is, we must provide counseling to them;
  - Incompetent should be exclude in the list of future parents.

EF3 : PROTECTING THE INTERESTS OF THE FUTURE CHILD

- The purpose of germline genome modification is to give birth a child who will not suffer the genetic condition her/his parent has.
- Our purpose is not making money, though it may be a result collateral with the purpose above and also we have to do cost accounting.
- Our purpose is not implementing eugenics which puts so-called “superior” (individual, family, ethnic group, race) on the priority of reproduction, and limits or even prohibits the reproduction of so-called “inferior”。

EF4 : PROTECTING SOCIAL INTERESTS

- Inheritable genome intervention may affect other people in the society, such as the moral status of these people is possibly threatened, and they would be stigmatized and discriminated:
  - Those who suffer genetics disease do not undergo genome editing; and
  - Their children who inherit genetic condition from their parent.
- Physicians and scientists have the moral responsibility for reaffirming that
  - Our work is to give birth a child without inheriting genetic condition;
  - We never ever stigmatize and discriminate against any people who suffer any genetic disease; and
  - They have same intrinsic value and human dignity with us as a human being/person, and put it into action.

GA1：PROFESSIONAL GOVERNANCE

- Relevant society such as Chinese Medical Association (CMA) and Chinese Society for Genetics and Medical Genetics should **develop the ethical guidelines** on genome modification by genome editing.
- Unfortunately. During the period of so-called “stem cell therapy” unruly situation, only Chinese Society for Diabetology affiliated with CMA published a declaration to require its members to conduct clinical trials before they use any stem cell therapy in clinical practices. The society is the only one which published such a declaration, all others kept in silence.

GA2 : INSTITUTIONAL GOVERNANCE

- **Capacity building** must be strengthened for IRB being competent to do ethics review on the protocols of genome editing, germline genome modification in particular. As an external review body IRB may be not quite competent to review the protocols of genome modification by genome editing, because the members of IRB do not have sufficient knowledge of genomics, genome editing techniques, and ethical issues they may raise, as well as the capability of analyzing and assessing the risks-benefits ratio.

GA3：REGULATORY GOVERNANCE

- For National Health Commission (MOH) :
  - Developing **special regulations** on applying genome editing in human reproduction;
  - the **licensing system** should be established;
  - The protocol of germline genome modification needs **double ethics review**: Institutional and Expert review.
  - The **system of the examination and assessment of IRB's** review of the protocol of germline genome modification should be established.

GA4 : LEGAL GOVERNANCE

- The existing regulations which prohibit the implantation of modified gamete or embryo into human reproductive tract be revised.
- The legislature will play critical role in the consensus reached by citizens and keeps communications with other countries.

GA 5: INTERNATIONAL GOVERNANCE

- The United Nations should convene a meeting among member states to discuss the genome editing in human reproduction for germline genome modification will change the gene pool of the mankind. Member states should reach a consensus .

Thank you very much for your attention