WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing

and the second second

and the second second

A LOOMED TO DESCRIPTION OF THE PARTY OF THE

Contraction of the second second

HUMAN GENOME EDITING: POSITION PAPER

1993 (1993) 1993 (1993)



World Health Organization

WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing

HUMAN GENOME EDITING: POSITION PAPER



WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing. Human Genome Editing: position paper

ISBN 978-92-4-003040-4 (electronic version) ISBN 978-92-4-003041-1 (print version)

© World Health Organization 2021

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (http://www.wipo.int/amc/en/mediation/rules/).

Suggested citation. WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: Position paper. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Sales, rights and licensing. To purchase WHO publications, see http://apps.who.int/bookorders. To submit requests for commercial use and queries on rights and licensing, see http://www.who.int/about/licensing.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

This publication contains the collective views of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing and does not necessarily represent the decisions or the policies of WHO.

Photo credit - Front cover: © iStock.com/Natali_Mis

Graphic design and layout by Trans.Lieu Company Ltd

Contents

Acknowledgements	iv
Executive summary	vi
Background information	1
Preventing premature use of human genome editing	2
Governance framework	2
Recommendations	3
Leadership by WHO and its Director-General	3
International collaboration for effective governance and oversight	4
Human genome editing registries	4
International research and medical travel	4
Illegal, unregistered, unethical or unsafe research and other activities	4
Intellectual property	5
Education, engagement, and empowerment	5
Ethical values and principles for use by WHO	5
Review of the recommendations	5

Acknowledgements

The governance framework and the recommendations on human genome editing form a pair of reports that have been developed by the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing.

These publications have been developed under the direction and coordination of Ms Katherine Littler (Colead, Health Ethics & Governance Unit), under the overall guidance of John Reeder (Director, Research for Health) and Soumya Swaminathan (Chief Scientist).

Dr Piers Millett (consultant, United Kingdom of Great Britain and Northern Ireland) provided support to the project and was the lead writer of the publications as well as the meeting reports of the Committee. Dr Emmanuelle Tuerlings (consultant, Switzerland) also provided support and contributed to the writing of the documents.

WHO wishes to thank the following individuals and organizations for their contributions to the development of these publications.

WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing

WHO is most grateful to the Co-Chairs, Dr Margaret Hamburg, former Commissioner of the U.S. Food and Drug Administration and former Foreign Secretary, National Academy of Medicine, United States of America and Justice Edwin Cameron, Inspecting Judge of Correctional Services, South Africa, and the members of the Committee for their invaluable guidance, expertise and great support throughout the project and the conceptualization and development of the three publications (by alphabetical order):

Dr Mohammed Alquwaizani, Saudi Food and Drug Authority, Kingdom of Saudi Arabia (member until 2 June 2020) Professor Ewa Bartnik, Universtiy of Warsaw, Poland Professor Françoise Baylis, Dalhousie University, Canada Professor Alena Buyx, the Technical University of Munich, Germany Professor Alta Charo, University of Wisconsin, United States of America Dr Hervé Chneiweiss, CNRS, INSERM, France Associate Professor Jantina De Vries, University of Cape Town, South Africa Dr Cynthia Holland, the Australian and New Zealand Infertility Counsellors Association, Australia Professor Maneesha S. Inamdar, Jawaharlal Nehru Centre for Advanced Scientific Research, India Professor Rozito Kato, Osaka University, Japan Professor Robin Lovell-Badge, The Francis Crick Institute, United Kingdom Dr Jamie Metzl, Atlantic Council & OneShared, United States of America Dr Ana Victoria Sánchez-Urrutia, SENACYT, Panama Professor Jacques Simpore, Université Ouaga I, Burkina Faso Professor Anne Wangari Thairu-Muigai, Jomo Kenyatta University of Agriculture and Technology, Kenya Professor Xiaomei Zhai Chinese, Academy of Medical Sciences & Peking Union Medical College, China

All authors and members of the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing declared their interests according to WHO standard procedures. None of the interests declared were found to be significant.

To the experts and organizations who participated in the in-person meetings, the online meetings and webinars and provided valuable inputs through sharing their experiences and insights on human genome editing. The Annexes of the Governance Framework and Recommendations on Human Genome Editing list the participants in meetings, consultations and webinars.

The many individuals and organizations who participated in the first and second online consultations on the governance framework on human genome editing. Their valuable inputs and comments have contributed to the development of the governance framework.

The technical contributions of colleagues at WHO headquarters: Dr Avni Amin, Dr Samvel Azatyan, Efstratios (Stratos) Chatzixiros, Dr Erika Dueñas Loayza, Mr Ghassan Karam, Dr Ivana Knezevic, Dr Olufemi Taiwo Oladapo, Dr Yuyun Maryuningsih, Dr Soumya Swaminathan, Dr Jacqui Stevenson, Professor John Reeder, Dr Andreas Reis, Dr Anna Laura Ross and Dr Si Hyung Yoo.

The authors of the two reports commissioned by the WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: Ms Nicola Perrin (independent consultant), Dr Güneş Taylor and Dr Christophe Galichet (The Francis Crick Institute), United Kingdom.

Colleagues at WHO headquarters Ms Elena Egorova, Ms Gloria Haselmann, Anne-line Nippierd Imbsen and Ms Sophie Spillard for their administrative support throughout the project. Special appreciation is also expressed to the external teams who provided administration support for the meetings that have been held in Singapore (14 November 2019) and in Cape Town, South Africa (24-26 February 2020).

WHO gratefully acknowledges the financial support provided by Wellcome Trust for this project and for the development of these publications.

Executive summary

The recent application of tools, such as CRISPR-Cas9 (clustered regularly interspaced short palindromic repeats; Cas9 nuclease), to edit the human genome with the intention of treating or preventing disease and the gaps in our scientific understanding, in addition to some of the proposed applications of human genome editing, raise ethical issues that have highlighted the need for robust oversight in this area. The COVID-19 pandemic has clearly demonstrated the importance of using new tools and methods to combat serious diseases and highlighted the potential benefits of human genome editing research. It also reminds us of the need to develop technology carefully, with robust testing and quality assurance measures in place to maximize benefit and minimize harm. The balance between benefit and harm, safety and speed, and innovation and access is relevant to all of human genome editing.

In December 2018, the World Health Organization (WHO) established a global, multidisciplinary expert advisory committee (the Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing, hereafter called the Committee) to examine the scientific, ethical, social and legal challenges associated with human genome editing (somatic, germline and heritable). The Committee was tasked to advise and make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. Its remit did not include a review of matters to do with safety and efficacy. Committee members were drawn from each of the WHO regions – Africa, the Americas, South-East Asia, Europe, Eastern Mediterranean and Western Pacific.

The 18 members of the Committee worked for two years and developed several products and new initiatives. The governance framework on human genome editing, along with the recommendations of the Committee, form a set of two publications that provide advice and recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. A position paper on human genome editing provides a summary of these two publications.

预览已结束, 完整报告链接和二维码如下:

https://www.yunbaogao.cn/report/index/report?reportId=5_23727

