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

Report of the fourth meeting

2–4 September 2020

WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: report of the fourth meeting, 2–4 September 2020

ISBN 978-92-4-003475-4 (electronic version)
ISBN 978-92-4-003474-7 (print version)

Suggested citation. WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: report of the fourth meeting, 2–4 September 2020. 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.

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1. Background

In December 2018, the World Health Organization (WHO) established a global, multidisciplinary expert advisory committee to examine the scientific, ethical, social and legal challenges associated with human genome editing (both somatic and germline).[1] The Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing includes members from Africa, the Americas, South-East Asia, Europe, the Eastern Mediterranean and the Western Pacific.[2]

The Committee has been tasked with advising and making recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing. During the course of its work, the Committee will review literature on current human genome editing research and its applications, consider existing proposals for governance and relevant ongoing initiatives, and solicit information about societal attitudes towards the different uses of this technology. The Committee will explore how best to promote transparent and trustworthy practices and how to ensure appropriate assessments are performed prior to any relevant work being undertaken.

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 avoiding disease has highlighted the need for robust oversight in this area. The Committee will work in a consultative manner and build on existing initiatives to develop a responsible and responsive governance framework for the application of genome editing technologies going forward. It will liaise with relevant United Nations and other international agencies and will communicate with academies of science and medicine and other national or professional bodies, patient groups and civil society organizations that have worked, or are working, in this area.

2. Past work

The Committee held its first meeting from 18 to 19 March 2019. The first meeting included a review of the current state of relevant science and technology and briefings on existing initiatives and reports relevant to its work. Participants also began to identify and discuss specific issues, mechanisms and stakeholders that could comprise, or contribute to the development of, a governance framework. The Committee also considered how these elements may differ at international, regional, national or local level. The group made three recommendations to the Director-General: (a) to develop a registry to provide a more structured mechanism for collecting and curating details of planned and ongoing relevant research and development; (b) that “it would be irresponsible at this time for anyone to

[1] https://www.who.int/groups/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing/about.

[2] https://www.who.int/groups/expert-advisory-committee-on-developing-global-standards-for-governance-and-oversight-of-human-genome-editing/about.

proceed with clinical applications of human germline genome editing", and that the Director-General should communicate this view to relevant regulatory bodies around the world; and (c) to enhance WHO's capacity to share information with, and collect information from, both technical and lay audiences. Each of these recommendations was aligned with one of the guiding principles adopted by the Committee: (a) transparency; (b) the responsible stewardship of science; and (c) inclusivity. A report of the meeting is available online.[3]

In a statement issued on 26 July 2019, the Director-General formally and publicly endorsed the Committee's recommendation that it would be irresponsible for anyone to proceed with clinical applications of human germline genome editing.[4] He stated that regulatory authorities in all countries should not allow any further work in this area until its implications had been properly considered. WHO has begun communicating this opinion to its regional and country offices.

The Committee held its second meeting from 26 to 28 August 2019. The second meeting focused on hearing additional views and insights relevant to the Committee's work. The meeting included updates on relevant activities in different countries and from national, regional, and international organizations, as well as briefings by external experts on aspects of its mandate. The Committee's working groups reviewed progress on establishing a registry of relevant research and development and responsible scientific stewardship. During closed sessions on the final day of the meeting, the Committee discussed a range of scenarios that could be used to help develop and test the governance framework, as well as opportunities for education, engagement and empowerment. The meeting outcomes included confirming the scope of the Committee's work; providing clearer rationale for including somatic human genome editing in the committee's mandate and in the online registry; revising and updating the guiding principles; establishing a phased approach to the development of the Registry; the creation of a working group on education, engagement and empowerment; plans for two rounds of online consultation to further expand opportunities for input into the Committee's work; and initial reflections on content for a governance framework. A report of the meeting is available online.[5]

The first online consultation ran from 15 January 2020 to 7 February 2020. The spread of COVID-19 increased significantly during this time, making the dissemination of the survey challenging. The Committee anticipated wider circulation than proved possible at the time.

The survey included 12 questions divided into four parts: (a) questions on who was providing a response; (b) questions on the general approach taken by the Committee; (c) questions on the draft governance framework being developed by the Committee; and (d) final comments – an open question for respondents to provide additional input for the Committee. Major themes appearing in the responses included concern over appropriate outreach to a wide

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[3] https://apps.who.int/iris/bitstream/handle/10665/341017/WHO-SCI-RFH-2019.01-eng.pdf.

[4] https://www.who.int/news-room/detail/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing.

[5] https://apps.who.int/iris/bitstream/handle/10665/341018/WHO-SCI-RFH-2019.02-eng.pdf.

audience to ensure consideration of social implications beyond technical or medical considerations; suggestions about integrating views of industry, bioethicists and governments; recognition of cross-border challenges to harmonization or coordination of policies; and the importance of ongoing consultation and transparency. Feedback was provided on a draft of the governance framework being developed by the Committee. Very few respondents identified elements in the framework they found to be unacceptable. Many comments included suggestions for improving the framework, such as additions or alterations to the proposed framework. A report of the consultation is available online.[6]

The Committee held its third meeting from 25 to 26 February 2020. The meeting focused on hearing the views and insights of those often excluded from international science policy processes. The meeting included contributions by African research organizations, community groups from Africa, and African bioethicists, as well as first-hand testimony from those affected by conditions that have been connected to human genome editing. The meeting was also briefed on satellite meetings supported by Committee members in other parts of the world. During closed working sessions, the Committee heard an initial overview of responses to its first online consultation; considered updates and reports from its working groups; continued to develop its governance framework; and developed plans for a second online consultation, taking into account lessons learned from its earlier consultation. The meeting outcome focused on revising and restructuring the governance framework in light of feedback. The Committee also considered how it might capture, in its future work, systemic issues connected to public health and sustainable development agendas that are likely to have a notable impact on the future development of human genome editing. A report of the meeting is available online.[7]

The second online consultation ran from 14 July 2020 to 19 August 2020. The survey included 12 questions divided into four parts: (a) questions on who was providing a response; (b) questions on the general approach to developing a governance framework; (c) questions on specific parts of the draft governance framework; and (d) final comments – an open question for respondents to provide additional input for the Committee. Responses received were largely positive, with wide support for the approach taken by the Committee, its efforts to be inclusive, differentiation between somatic and germline human genome editing, and improvements in the draft since the first online consultation. Some negative responses were received, with concerns being raised over the length of the framework and possible repetitions, and calls to focus more heavily on specific aspects of human genome editing. A very limited number of comments raised concerns over the approach taken by the Committee. Feedback on the draft governance framework included a large number of specific proposals for additions, alterations, or other edits for the Committee to consider.

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[6] https://apps.who.int/iris/bitstream/handle/10665/344007/9789240032446-eng.pdf.

[7] Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing (who.int).

3. Work of the meeting

From 2 to 4 September 2020, members of the Committee met remotely. A separate topic was addressed each day.

On 2 September, the Committee was briefed by the International Commission on the Clinical Use of Human Germline Genome Editing. The co-chairs and members of the Commission presented their report *Heritable human genome editing*.[8] Members of the Committee then had the opportunity to discuss the report and key findings with members of the Commission. The discussions focused heavily on Part 5 of the report and associated recommendations on national and international governance of human germline genome editing. Members of the Committee then met in a closed session to reflect on the day's discussions and prepare for the next day.

On 3 September, the Committee was briefed by the WHO programmes on strategic foresight and regulatory harmonization. The Committee was then briefed by WHO on a provisional analysis of the responses to the second online consultation. The briefing included details of the number and diversity of responses, a summary of key findings, and major trends in responses to the different parts of the survey. Given the number and depth of responses received and the time available, it was not possible to review all of the feedback received; that was therefore provided to members of the Committee for their review and analysis after the meeting. The Committee agreed a workplan to revise the draft governance framework in light of the responses received and its subsequent discussions.

On 4 September, the Committee reviewed expected outputs from its work and began developing an outline for its final report. The Committee discussed and took decisions on the timeline for future work and on appropriate ways of working. The Committee heard updates from its working groups on the registry, responsible stewardship of science, and education, engagement, and empowerment. The members of the Committee considered the reporting of unregistered, unethical or illegal research and development activities, and how to prevent instances where researchers or companies located relevant activities in countries with weaker regulatory infrastructure for no reason other than to avoid regulation and ethics guidelines that existed in other countries. There was also an initial discussion of possible international options for strengthening governance of human genome editing. The Committee also reviewed and agreed upon further rounds of webinars to fill gaps in its evidence gathering