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

Report of the third meeting

Cape Town, South Africa, 25–26 February 2020

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ISBN 978-92-4-002849-4 (electronic version)
ISBN 978-92-4-002850-0 (print version)

Suggested citation. WHO Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: report of the third meeting, Cape Town, South Africa, 25-26 February 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

The World Health Organization (WHO) has 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, Asia, Europe, the Middle East, Oceania, North America and South America.[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 on 18–19 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 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 those elements might 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

[1] Expert Advisory Committee on Developing Global Standards for Governance and Oversight of Human Genome Editing: 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.

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 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 those 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 on 26–28 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 and 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]

3. Work of the meeting

On 25–26 February 2020, 14 of the 18 members of the Committee and seven invited experts (Annex) met in Cape Town, South Africa.

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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.

In its first substantive session, the meeting was briefed by individuals, organizations and peoples on human genome editing, including:

- Kwanele Asante-Shongwe, Secretary-General Elect of the African Organization of Research and Training in Cancer, South Africa;
- Collin Louw, Chairperson, Director of the San Council, South Africa;
- Leana Snyder, Director of the San Council, South Africa;
- Brian Watermeyer, Senior Research Officer, Department of Health and Rehabilitation Sciences, University of Cape Town, South Africa;
- Glaudina Loots, Director for Health Innovation at the Department of Science and Innovation, South Africa;
- Ames Dhai, Founding Director of the Steve Biko Centre for Bioethics, Professor of Bioethics, Faculty of Health Sciences, University of the Witwatersrand, South Africa;
- Judith McKenzie, Head of Division of Disability Studies, University of Cape Town, South Africa.

At its second substantive session, the meeting was briefed on satellite meetings supported by Committee members, including the Global Forum on Bioethics in Research meeting in Singapore in November 2019 and the Sickle Cell Disease-Genome Editing Consultation held on 24 February 2020 in Cape Town, South Africa. Members of the Committee also provided updates on relevant initiatives. The Committee heard an initial overview of responses to its first online consultation.

The afternoon of the first day and the entire second day of the meeting were dedicated to closed working sessions. The Committee began by hearing updates to reports from the working groups. It then held sessions in which it further developed a governance framework, explored further engagement activities relevant to its mandate, and expanded on its plans for a second online consultation.

During the final working sessions of the meeting, the Committee met again in private to consider its workplan and next steps, including agreeing on an intersessional workplan and an outline for its fourth meeting.

4. Summary of discussions

The Committee affirmed that somatic and germline genome editing raise different ethical issues that need to be distinguished. The Committee also acknowledged that ethical discussions on somatic and germline genome editing would impact the formulation of governance frameworks in different ways. The Committee reiterated that the scope of its work covered both human somatic and germline genome editing.

Although ethical issues associated with somatic genome editing might not be unique to genome editing, the Committee acknowledged that such issues remained important and needed to be further addressed. For example, the Committee recognized that relatively few

countries had established an appropriate translational pathway for somatic interventions involving human genome editing, with robust regulation and oversight to ensure patient safety and public confidence.

The Committee heard arresting testimonies and presentations from patients' rights advocates, people living with disabilities and an indigenous First Nations representative council. In addition, an Africa-based bioethicist and representatives of the South African Medical Research Council and of the South African Government afforded significant ethical and institutional perspectives on the opportunities, concerns and governance perspectives related to human genome editing.

Ms Kwanele Asante-Shongwe is a lawyer, bioethicist, person living with medication-induced heart disease and bipolar mood disorder, and patient advocate. The salient perspective she provided was that, while somatic genome editing offered very considerable benefits to patients, from a patient's perspective vexing questions regarding informed consent, justice, equity and accessibility had first to be addressed. She called for "distributive justice and fairness in the allocation of global genome research development funding for black African scientists and scientists from other minorities populations currently underrepresented in biomedical research". Ms Asante-Shongwe highlighted "the need for justice and fairness in the distribution of global research funds and research opportunities to ensure that African populations are studied by scientists who resemble them and who understand their sociocultural context".

Ms Leana Snyder and Mr Collin Louw, representatives of the San Council of South Africa (representing South Africa's First Nations indigenous people, the San or Bushmen), underscored the unforeseen consequences that apparent technological advances might entail for humans, plants and animals. They referred to the Committee the San Code of Research Ethics (2017) and its sister code, the Global Code of Conduct for Research in Resource-Poor Settings, adopted by the European Commission in 2018, which aimed to counter "ethics dumping", whereby practices that would be forbidden in the researcher's own jurisdiction were undertaken in generally resource-poor settings that did not forbid them. Both codes embraced principles of justice, care, honesty, fairness, respect and process observance.

The meeting also heard from a disabled persons' rights advocate living with severe congenitally impaired vision. Dr Brian Watermeyer, of the Division of Disability Studies at the University of Cape Town, is a trained clinical psychologist, patient advocate, and disability studies researcher. He cautioned the Committee against harmful consequences that the drive to "cure" might have for disabled persons. He urged the Committee to reflect with care and humility on the meanings its recommendations and report might communicate, and the potentially damaging discourses of hope and denigration it might unwittingly support. Instead, the Committee should pursue inclusive, humane goals in regulating somatic genome editing, with clarity about what is possible, with discussion, inclusive at all stages of disabled people, couched in an awareness of real, functional lives lived by disabled persons, and which gives central place to economic questions of access and power. The discussions fostered by the Committee should at all stages be inclusive of disabled people.

On behalf of the South African Department of Science and Innovation, Ms Glaudina Loots illuminated the regulatory and ethical framework created by the South African Genetically Modified Organisms Act of 1997, the National Health Act of 2003 and the 2018 consensus study of the Academy of Science of South Africa. Within the legislative framework, the consensus study envisaged building relationships and stakeholder engagement. Guiding principles were respect for persons and sound stewardship of scientific innovation. The Department's Precision Medicine Programme sought better ways to use a patient-centric approach to create sustainable health care. Indispensable for this was a strong regulatory framework for somatic genome editing.

Two representatives of the South African Medical Research Council, Dr Mongezi Mdhluli and Dr Seeiso Koali, also made brief interventions. Dr Mdhluli emphasized that, in developing regulations pertaining to human genome editing, it was important to involve a wide range of departments and stakeholders. He stated that research in new technology development should ensure that research was not only on the participants but also with the participants and for the participants. Dr Koali noted that, in relation to research participants, the objective was not merely to obtain a signature on an informed consent form, but also to ensure that substantive respect was afforded to the participant's human dignity.

Professor Ames Dhai urged that the Committee's quest should be to harness technologies for improvement of health for all, and not just for a very few. Currently, South Africa lacked an ethical legal framework for research into and clinical applications of genome editing. The regulatory framework must be informed by ethics and allow access to interventions for all. Her presentation underscored the marginalization of Africa and African patients' needs. She said that the Academy of Science of South Africa had established a working group with multidisciplinary experts and government representatives to develop a national framework for governance of genome editing.

Professor Judith McKenzie, the Head of Division of Disability Studies at the University of Cape Town, underlined that diversity brought richness. She said that the range of disabilities and the needs of disabled people made us think creatively about diversity and difference. She stated that "disability is difficult to deal with because it reminds us of our own vulnerability, but vulnerability is part of being human and cannot be ignored". She suggested that "the discourse of pain and suffering around disability eclipses the positive experiences that can, and do, arise as in, for example, families who have children with Down syndrome"