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
## Contents

1. Background .......................................................................................................................... 1
2. Past work ............................................................................................................................... 1
3. Work of the meeting ............................................................................................................... 2
4. Summary of discussions ....................................................................................................... 3
5. Outcomes ............................................................................................................................... 5
6. Future work of the Committee ............................................................................................. 6

Annex. List of participants ........................................................................................................ 8
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). 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.

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

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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.


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”.

The Committee agreed that the insights gathered, and contributions received, during its third meeting would shape its future work.

5. Outcomes

The Committee reflected on responses to its first online consultation, as well as lessons learned from its conduct. Members of the Committee would review the responses in detail after the conclusion of the meeting. Key insights from responses would shape the Committee’s future work, in particular the development of the governance framework, and would contribute to education, engagement and empowerment. The Committee agreed to
simplify the processes used for its second consultation, to expand its distribution, and to extend the length of the consultation. Members of the Committee would continue to work with WHO in the development of the next round of consultation.

The Committee agreed that its governance framework would include the following.

- A range of elements or tools to help identify challenges and mechanisms, and to engage institutions, organizations and peoples that might need to be involved in governance efforts. Those would need to be revised and updated in light of responses to the first online consultation.

- Guidance for governance practitioners on the use of those tools. Such guidance could provide insights into how the tools might be adapted to specific contexts, and illustrative questions to be considered when developing governance measures.

- Examples of how governance measures could be implemented in different contexts to effectively address key issues, for example by developing illustrative scenarios. Those scenarios would explore a limited number of potential developments discussed by members of the Committee. The scenarios would be based on current real-world examples, including sickle cell disease, Huntington’s disease and muscular dystrophy, as well as longer-term, more speculative events such as enhancements for space travel and future fertility clinics.

- Analyses of how the governance framework and associated governance measures might be implemented. Those would include metrics that provide insights into the impact of the framework and progress to build relevant capacities, as well as arrangements for reviewing and updating the governance framework.

- A glossary that clarified what key terms meant and how they were being used by the Committee. The Committee agreed on the importance of continuing to work with relevant organizations, such as the International Commission on the Clinical Use of Human Germline Genome Editing and national standard-setting organizations.

During its work, the Committee had identified a number of systemic issues connected to public health and sustainable development agendas that related to its charge. The Committee recognized that those issues were likely to have a notable impact on future development of human genome editing. The Committee further recognized that those issues were unlikely to be resolved through actionable recommendations to the Director-General. The Committee would continue to reflect on how its work and recommendations would help contribute to progress in those areas.

6. Future work of the Committee

The Committee agreed that its next meeting would take place in September 2020. The next meeting of the Committee would focus on finalization of Committee outputs and recommendations to the Director-General.
In advance of its final meeting:

- WHO would facilitate a second online consultation on the Committee’s outputs;
- the working groups would continue to explore their respective topics and help refine relevant outputs;
- the Committee would continue to consult with relevant groups, in particular through the use of remote meeting tools.
Annex. List of participants

Third Committee meeting, 25–26 February 2020, Cape Town, South Africa

Committee members

Professor Ewa Bartnik  
Professor  
Institute of Genetics and Biotechnology  
University of Warsaw  
Warsaw  
Poland

Professor Françoise Baylis  
Research Professor  
Dalhousie University  
Novel Tech Ethics  
Halifax, Nova Scotia  
Canada

Professor Alena Buyx  
Professor of Ethics in Medicine and Health Technologies  
Director  
Institute for History and Ethics in Medicine  
Technische Universität München  
München  
Germany

Justice Edwin Cameron (Co-Chair)  
Inspecting Judge of Correctional Services  
Constitutional Court  
Johannesburg  
South Africa

Professor Robin Alta Charo  
Warren P. Knowles Professor of Law and Bioethics  
University of Wisconsin Law School  
Madison, Wisconsin  
United States of America
Dr Hervé Chneiweiss  
Directeur du laboratoire Neuroscience Paris Seine – IBPS  
Bâtiment A3 pièce 336 Case courrier 2  
Equipe Plasticité Gliale et Tumeurs cérébales  
UMR8246 CNRS/U1130 Inserm/Sorbonne Université  
Campus Pierre et Marie Curie  
Paris  
France

Dr Jantina De Vries  
Associate Professor Bioethics  
Department of Medicine  
University of Cape Town  
UCT Centre for Clinical Research  
Groote Schuur Hospital  
Cape Town  
South Africa

Dr Margaret Hamburg (Co-Chair)  
Former Commissioner of the U.S. Food and Drug Administration and  
Former Foreign Secretary, National Academy of Medicine  
Washington, D.C.  
United States of America

Professor Maneesha S. Inamdar  
Professor and Dean  
Jawaharlal Nehru Centre for Advanced Scientific Research  
Jakkur, Bangalore  
India

Professor Kazuto Kato (online)  
Professor  
Department of Biomedical Ethics and Public Policy  
Graduate School of Medicine, Osaka University  
Suita, Osaka  
Japan
Professor Robin Lovell-Badge  
Group Leader in Stem Cell Biology  
Francis Crick Institute  
London  
United Kingdom

Dr Jamie Metzl  
Senior Fellow  
Atlantic Council & OneShared.World  
New York City  
New York  
United States of America

Dr Ana Victoria Sánchez-Urrutia  
Senior Office Advisor  
Bioethics, SENACYT  
Panama City  
Panama

Professor Anne Wangari Thairu-Muigai  
Director  
Kenya Plant Health and Inspection Services and  
Commissioner, Commission for University Education  
Nairobi  
Kenya

Experts

Kwanele Asante-Shongwe  
Secretary-General Elect  
African Organization of Research and Training in Cancer (AORTIC)  
South Africa

Professor Ames Dhai  
Founding Director of the Steve Biko Centre for Bioethics  
Professor Bioethics, Faculty of Health Sciences  
University of the Witwatersrand  
Johannesburg  
South Africa
Dr Seeiso Koali  
Research Integrity Officer  
South African Medical Research Council  
Cape Town  
South Africa

Glaudina Loots  
Director for Health Innovation  
Department of Science and Innovation  
Pretoria  
South Africa

Professor Judith McKenzie  
Head of Division of Disability Studies  
University of Cape Town  
Cape Town  
South Africa

Dr Mongezi Mdhluli  
Chief Research Operation Officer  
South African Medical Research Council  
Cape Town  
South Africa

Collin Willem Louw  
Chairperson of the San Council of South Africa  
Cape Town  
South Africa

Leana Snyder  
Director of the San Council of South Africa  
Cape Town  
South Africa

Dr Brian Watermeyer  
Senior Research Officer, Department of Health and Rehabilitation Sciences  
Academic staff member of the Division of Disability Studies  
University of Cape Town  
Cape Town  
South Africa
Rapporteurs

Dr Piers Millett
Dr Emmanuelle Tuerlings

WHO Secretariat

Ms Katherine Littler