

# Human Genome Editing



## WHO expert advisory committee on developing global standards for governance and oversight of Human Genome editing

Margaret A. Hamburg, M.D.

November 2019

# Outline

- Introducing the expert advisory committee
  - Charge
  - Method of work
  - Membership
- Work to date
  - First and second meeting
- Plans for the future
  - Future work of the Committee
  - Timeline

# Advisory committee

## *Charge to the committee*

- To examine the scientific, ethical, social & legal challenges associated with human genome editing
  - Focus on both somatic and germline editing
- To advise WHO DG & make recommendations on appropriate institutional, national, regional and global governance mechanisms for human genome editing
- Toward this end, committee activities include:
  - Review of relevant literature
  - Consideration of existing & proposed governance measures
  - Soliciting societal attitudes to the use of technologies
  - Exploration of methodologies for ensuring transparent & trustworthy practices

# Advisory committee

## *Method of work*

- Work in a consultative manner
- Build on existing initiatives
- Liaise with relevant UN & other international agencies and organizations
- Communicate with other relevant bodies, including:
  - Academies of Science and Medicine
  - National or professional bodies
  - Patient groups
  - Civil society organizations
  - Private sector entities

# Advisory Committee



Committee Composition

## Diverse Membership

All 6 WHO regions are represented:

Countries (15): Australia, Burkina Faso, Canada, China, France, Germany, India, Japan, Kenya, Panama, Poland, Saudi Arabia, South Africa, UK, US

Members reflect a wide range of disciplines/areas of expertise:

Regulators, Scientists (genetics, neurology, oncology, stem cell, developmental biology), Clinicians, Philosophy, Bioethics, Legal, Technology Futurist, Geopolitics

# Advisory committee

## *Membership*



**Co-Chair**  
Margaret A. (Peggy) Hamburg  
(USA)



**Co-Chair**  
Cameron Edwin  
(South Africa)

# Advisory committee

## *Membership*



Mohammed Alquwaizani  
(Saudi Arabia)



Ewa Bartnik  
(Poland)



Françoise Baylis  
(Canada)



Alena M. Buyx  
(Germany)



R. Alta Charo  
(USA)



Hervé Chneiweiss  
(France)



Jantina De Vries  
(South Africa)



Cynthia Holland  
(Australia)

# Advisory committee

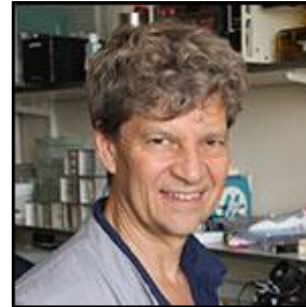
## *Membership*



Maneesha Inamdar  
(India)



Kazuto Kato  
(Japan)



Robin Lovell-Badge  
(United Kingdom)



Jamie Metz  
(USA)



Ana Victoria  
Sánchez-Urrutia  
(Panama)



Jacques Simpore  
(Burkina Faso)



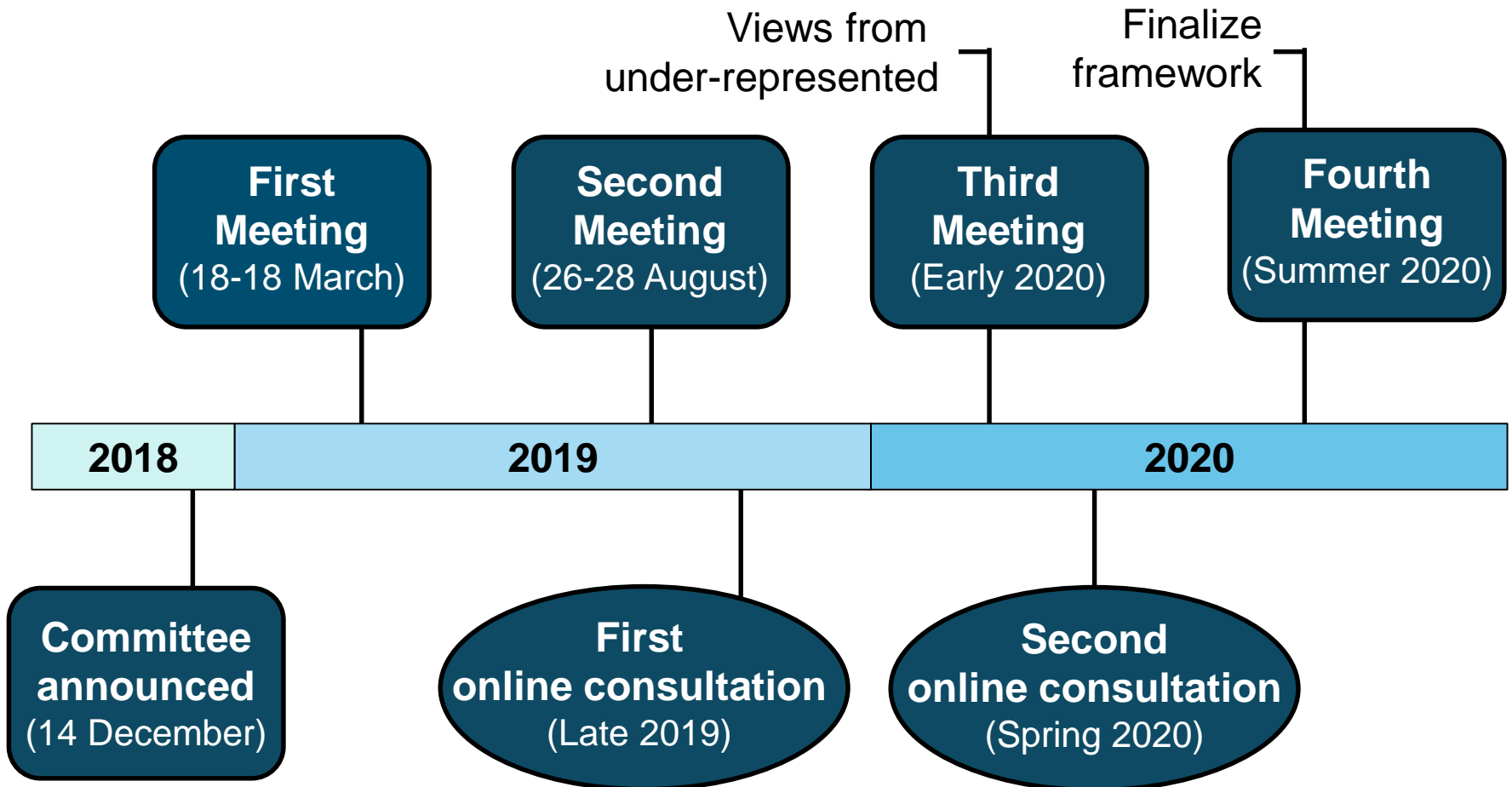
Anne Thairu-Muigai  
(Kenya)



Xiaomei Zhai  
(China)



# Timeline



# First meeting

*18-19 March 2019*

The first meeting of the committee included:

- Briefings on technical updates in genome editing
- Briefings on existing initiatives & progress to date
- Introductions to background documents produced by WHO
- Working sessions to identify elements important for a governance framework
- Closed sessions for the committee to:
  - Discuss information gathered
  - Plan future work

It produced 3 recommendations

# First meeting

## *Recommendation 1*

### **...a more structured mechanism for collecting and curating details of planned and ongoing research:**

- Recommended WHO established a registry of relevant research
- Established a working group to design architecture of registry, including:
  - Types of research to be covered
  - Metadata to be collected to describe research
  - A template will be presented to the next meeting of the group
- Aligns with principle of transparency and failing to provide info “must be considered a fundamental violation of responsible research”
- Work with funders & publishers to encourage submission of research
- Needs to be able to include products and clinical applications in future

# First meeting

## *Recommendation 2*

**...“it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing” :**

- To do so would be inconsistent with the principle of responsible stewardship of science
- All those conducting or aware of relevant research and development need to engage with the committee immediately
- Important to understand what has not been published/announced to date, including:
  - negative findings
  - inconclusive findings
  - successful efforts

# First meeting

## *Recommendation 3*

**...input from the broadest possible range of stakeholders and explore opportunities for an open, online mechanism for seeking input:**

- Requested the DG to increase WHO's capacity to share information with, and collect information from, both technical and lay audiences:
  - Enhanced website;
  - Targeted outreach to regional and country offices
- Use WHO's regional & country offices to canvass societal views on human genome editing & act as a vehicle for engagement
- Make full use of WHO's ability to operate in multiple languages
- Explore language-independent resources, such as cartoons and memes

# First meeting

Toward developing a governance framework: UNESCO definition

...structures and processes that are designed to ensure accountability, transparency, responsiveness, rule of law, stability, equity and inclusiveness, empowerment, and broad-based participation. Governance also represents the norms, values and rules of the game through which public affairs are managed in a manner that is transparent, participatory, inclusive and responsive

<http://www.ibe.unesco.org/en/geqaf/technical-notes/concept-governance>

# First meeting

## *Governance framework*

### **The committee determined that a governance framework must:**

- Identify relevant issues, a range of specific mechanisms to address them, and be developed in collaboration with the widest possible range of stakeholders.
- Be scalable, sustainable and appropriate for use at the international, regional, national and local levels.
- Work in parts of the world where there are weaker systems of regulation of scientific and clinical research and practice, and where genome editing may not yet be pursued with great intensity.
- Provide all those responsible for the oversight of genome editing with the tools and guidance they need.

# Statement by the Director-General

*26 July 2019*



“Human germline genome editing poses unique and unprecedented ethical and technical challenges,” said WHO Director-General Dr Tedros Adhanom Ghebreyesus. “I have accepted the interim recommendations of WHO’s Expert Advisory Committee that regulatory authorities in all countries should not allow any further work in this area until its implications have been properly considered.”

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



# Second meeting

*26-28 August 2019*

The second meeting of the Committee included:

- Briefings on existing initiatives, existing regulatory regimes & progress to date
- Briefings by the two Committee's working groups (Registry and Responsible stewardship of science)
- Presentations from external experts on:
  - Governance mechanisms, such as those in place for other technologies
  - The scope of relevant work – i.e. enhancement
  - Issues relevant to commercial development
- Working sessions on the development of a governance framework
- Closed sessions to discuss information gathered and plan future work

# Second meeting

## *Outcomes*

- **Confirmed importance of scope**, including both somatic as well as germline.
- **Principles of fairness and social justice** were added to the three principles identified at the first meeting.
- **Registry** – support for a pilot phase, including engagement.
- **Responsible Scientific Stewardship** – agreement to progress work on broad framework, including several key areas of specific concern:
  - Risk havens/ethics dumping
  - Whistleblowing

# Second meeting

## *Outcomes*

- Established 2 new working groups
  - **Education, Engagement & Empowerment**
  - **Oversight**
- Committed to **two online consultations**
  - autumn 2019: to seek input for the development of a governance framework and to gather additional views relevant to the Committee's work
  - spring 2020: to help test a draft of the governance framework

# Second meeting

## *Governance framework*

- In addition to the first meeting's recommendations on governance, the Committee identified the **core elements** of a governance framework, including:
  - key issues to be considered when developing oversight regimes
  - different mechanisms that may be used individually or collectively as part of governance efforts
  - a wider range of various actors to be involved
- The Committee began to explore a range of **scenarios** to highlight the key issues, to identify challenges to governance and to foster greater engagement.
- The Committee also identified a number of **principles** to guide both their work and future efforts on the effective governance of human genome editing technology, including:
  - Transparency, Inclusiveness, Responsible stewardship of science, Fairness and Social justice.

# Working groups

## 1. Registry

- Scope
- Format

## 2. Responsible stewardship of science

- Responsible practice
- Risk havens
- Whistleblowing

## 3. Oversight issues

- Reviewing national governance measures obtained by WHO
- Scenario development
- Terminology

## 4. Education, engagement, and empowerment

- Opportunities to build capacity
- Relevant partners to work with

# A few status updates

Registry

Online consultations

Other consultations

Future work

# Registry

## *Steps taken to date*

- Make use of tools that underpin WHO's International Clinical Trials Registry Platform
- Current platform already contains entries relevant to human genome editing
- WHO developed draft templates & keywords to gather information
- Continuing to work to develop front end
- First phase to focus on clinical applications
- Subsequent work to add relevant basic research
- Pilot registry beginning in collaboration with communities most likely to generate relevant work
- Work with scientific community, funders and publishers such that failure to register research would be viewed as a violation of responsible scientific conduct

# Online consultation

*...to expand the views that feed into work on governance of human genome editing*

- Two rounds:
  1. Autumn 2019 - to seek input for the development a governance framework
  2. Spring 2020 - help test a draft framework before it is provided to the DG
- Targeted efforts to engage:
  1. Groups particularly relevant to human genome editing
  2. Voices often under-represented in international science policy consultations
- Education, engagement, and empowerment WG developing tools & plans
- WHO to make use of country and regional offices, social media & all available channels to promote the consultation



# Other consultation

*...to further expand the views that feed into work on governance of human genome editing*

- Work with Academy Commission to learn from their information call and consultations
- Participation in various relevant meetings and conference
- Meetings with interested parties, including scientific organizations, professional societies, consumer groups
- Outreach to regulatory authorities/health officials in WHO Member States

# Future work of the Committee

- Views gathered by the first online consultation (Late 2019) will be reviewed at the third Committee meeting (February 2020).
- The third Committee meeting will focus on expanding the number of voices contributing to the Committee's work.
- The 4 working groups will continue to work on areas identified by the Committee.
- Committee will continue to consult and respond to emerging issues (scientific, ethical, policy/program or other)

# Support to WHO Committee ongoing work

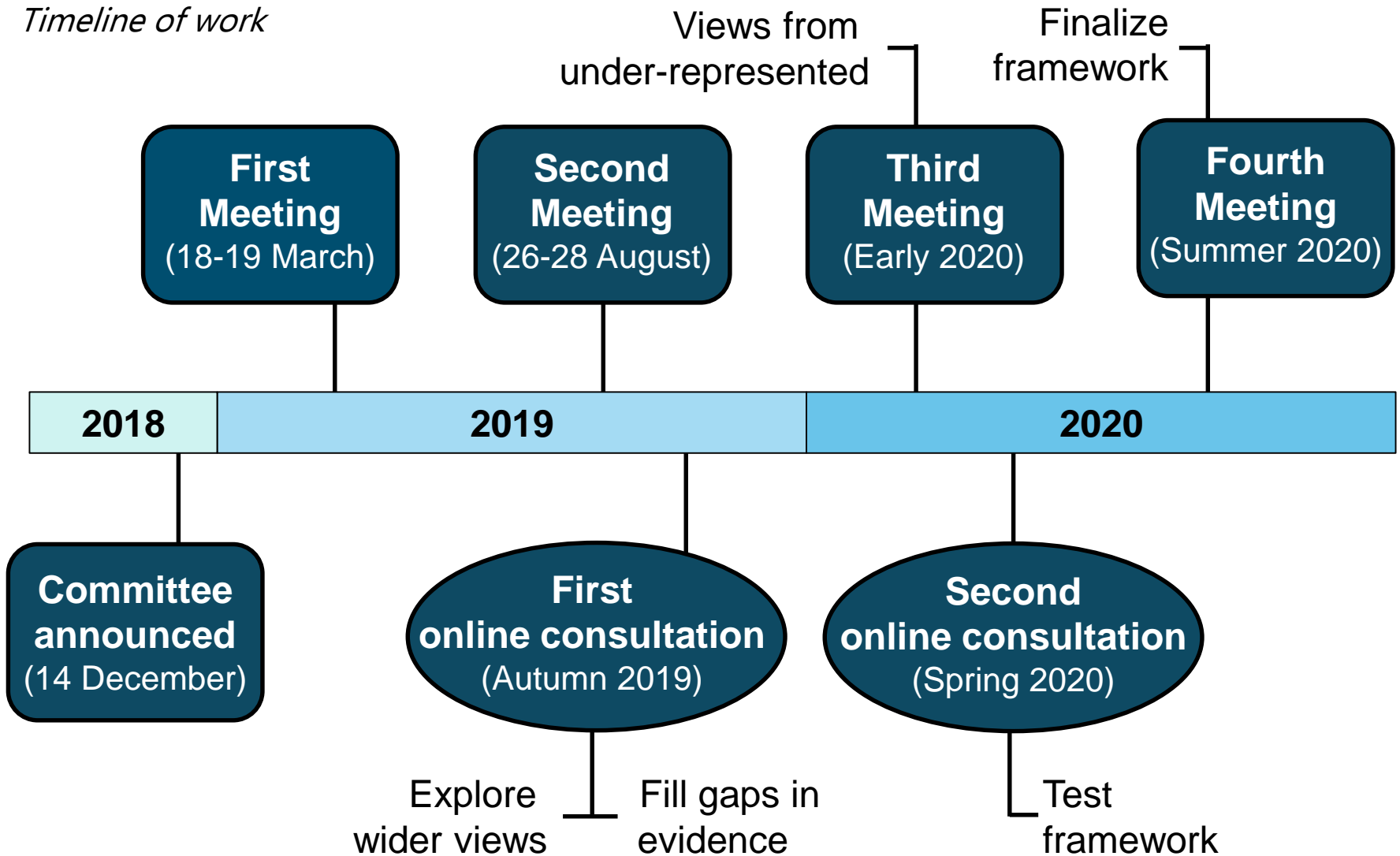


## The Case of Dr Rebrikov

- On June 10, 2019: Dr Denis Rebrikov, a Russian molecular biologist, announced his plans to alter CCR5 gene with CRISPR to “create gene-edited babies resistant to HIV” ([Nature, 10 June 2019](#)).
- On July 26, 2019: the WHO Director General issued a statement supporting the recommendation of the WHO Expert Advisory Committee, that “it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing” and “advised regulatory or ethics authorities to refrain from issuing approvals concerning requests for clinical applications for work that involves human germline genome editing.”([WHO Statement, 26 July 2019](#))
- On September 29, 2019: it is reported that Dr Rebrikov is now studying GJB2 gene, which is associated with deafness, and that Russian scientists and officials met to discuss his plans. ([Bloomberg, 20 Sept 2019](#); [Science, 21 Oct 2019](#)).
- On October 18, 2019: Dr Rebrikov declared having started to edit GJB2 gene in human eggs donated by woman who can hear “to allow some deaf couples to give birth to children without a genetic mutation that impairs hearing.” Dr Rebrikov does not intend to “implant gene-edited embryos until he gets regulatory approval” ([Nature, 18 Oct 2019](#)).
- In October 2019: the Russian Health Minister announced that “any clinical use of editing technologies of the genome of human embryos and germ cells is premature”. The Russian statement also supported the WHO position, which “should be decisive in the formation of country policies in this area.”

# Plans for the future

*Timeline of work*



# Thank you.



**WHO**

20, Avenue Appia  
1211 Geneva

Switzerland

[www.who.int](http://www.who.int)