Human Genome Editing

World Health Organization

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

13 August 2019

Margaret Ann Hamburg, Co-Chair

Outline

- Introducing the expert advisory committee
  - Charge
  - Method of work
  - Membership
- Work to date
  - First meeting
- Plans for the future
  - Timeline
  - Second meeting
- Opportunities to collaborate

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
- To this end the committee will:
  - Review relevant literature
  - Consider existing & proposed governance measures
  - Solicit societal attitudes to the use of technologies
  - Explore 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
- Communicate with other relevant bodies, including:
  - Academies of Science and Medicine
  - National or professional bodies
  - Patient groups
  - Civil society organizations

Advisory Committee

Committee Composition

Diverse Membership

All WHO regions and continents (except Antarctica) 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)

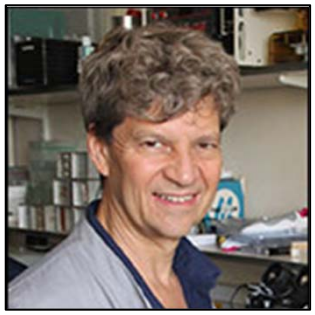
Co-Chair
Cameron Edwin
(South Africa)

Advisory committee

Membership

Maneesha Inamdar
(India)

Kazuto Kato
(Japan)



Robin Lovell-Badge
(United Kingdom)

Jamie Metzl
(USA)

Ana Victoria
Sánchez-Urrutia
(Panama)

Jacques Simpore
(Burkina Faso)

Anne Thairu-Muigai
(Kenya)

Xiaomei Zhai
(China)

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)

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 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

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. MOU4
- Provide all those responsible for the oversight of genome editing with the tools and guidance they need. MOU5

Slide 13

MOU4 I think that "traditionally" may imply a pattern and I am not sure whether there is a need to add such element here. For instance, some countries may have more permissive regulations than others and, at the same time, be very active in genome editing R&D. The governance framework needs to be relevant for them as well. So maybe just write "where there is weaker regulation".
E. Tuerlings, 7/25/2019

MOU5 Very nice bullet point!
E. Tuerlings, 7/25/2019

Statement by the Director-General

26 July 2019

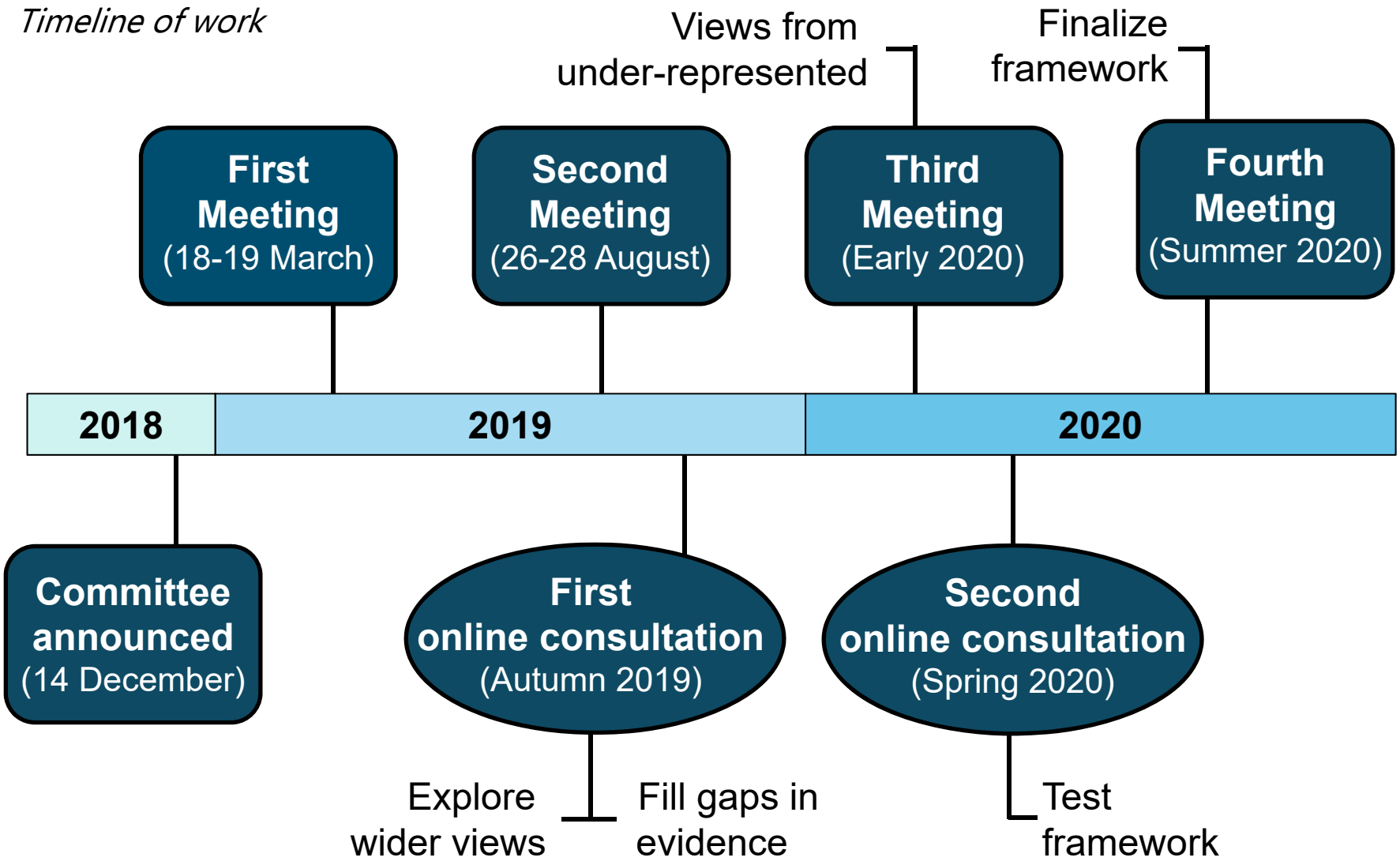
Committee Interim Finding: “it would be irresponsible at this time for anyone to proceed with clinical applications of human germline genome editing.”

WHO supports this interim recommendation and advises regulatory or ethics authorities to refrain from issuing approvals concerning requests for clinical applications for work that involves human germline genome editing

“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.”

Plans for the future

Timeline of work



Plans for the future

Second meeting

At their next meeting, the committee plans to:

- Consider examples of existing regulatory regimes
- Gather evidence from external experts, including on:
  - Governance mechanisms, such as those in place for other technologies
  - The scope of relevant work – i.e. enhancement
  - Issues relevant to commercial development
- Continue to develop elements for a governance framework
- Finalise plans for an online consultative process

Opportunities to collaborate

What we would like to see for the NASEM commission

Aspects of what we hope to be able to leverage from your work:

- Better understanding of the science of human genome editing
- Technical aspects (and related ethical aspects), such as:
  - Insights concerning translational pathways
  - Elements of responsible regulatory review (e.g. how to assess efficacy; how to determine safety; analysis of risk/benefit assessments; long-term follow-up; differential characteristics of different kinds of germline change)
- Help us best define the universe of experiments and clinical interventions that should be submitted to WHO Registry; strategies to enhance compliance

What we hope to be able to input into your work:

- International governance and regulatory elements
- Soliciting broad societal views on the use of these technologies

MOU9

Opportunities to collaborate

Points of convergence

Specific opportunities to work together might include:

- Mutual briefings of NASEM's international commission and WHO's expert advisory committee (including at our 3rd meeting planned for early 2020)
- Special convenings around specific topic areas
- Contributing to each others information gathering processes
- Collaborating to raise awareness of the issue, improve communication/information dissemination and foster public dialogue

Risks if we fail to work together:

- Confusing or contradictory messaging
- Competition for scarce resources resulting in less progress than possible
- Gaps that enable irresponsible research or application resulting in harm
- Long term damage to responsible application of genome editing technologies

MOU9 While each committee has a different mandate and different responsibilities, another potential risk of failing to work together could be the loss of trust and confidence of the public and of the health authorities.

E. Tuerlings, 7/25/2019

Thank you.

World Health Organization

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