Human Genome Editing

World Health Organization

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

November 2019

Robin Lovell-Badge, Member

Outline

- Introducing the expert advisory committee
  - Charge
  - Method of work
  - Scope
  - Membership
- Work of the Committee
  - Timeline
  - Working groups
  - Statement
  - Registry
  - Governance framework

Governance:

…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

Advisory committee

Charge to the committee

- Examine scientific, ethical, social & legal challenges
- Advise WHO DG & make recommendations
- Focus on appropriate governance mechanisms (institutional, national, regional and global)
  - not details of safety, efficacy and the clinical pathway
- Review relevant literature
- Consider existing & proposed governance measures
- Solicit societal attitudes to use of technologies
- Ways to ensure 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

Scope

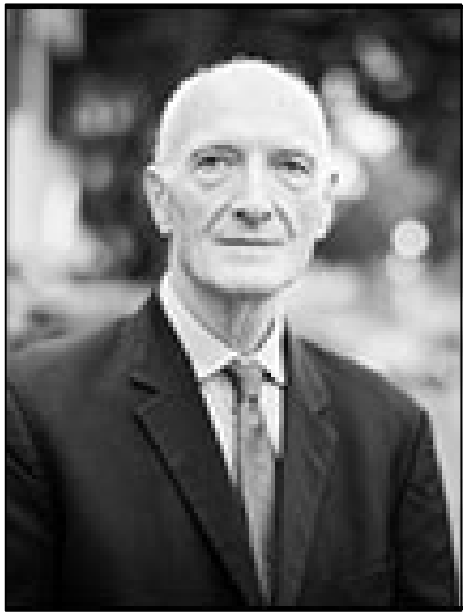
Both somatic and germline human genome editing

- Consensus agreement on the need to include somatic genome editing, because:
  - Trials have already begun and it has potential relevance to many individuals affected by genetic disease, cancer, etc
  - Regulatory and governance gaps
  - Concerns about inappropriate use
  - Concerns regarding rogue clinics exploiting regulatory gaps in some parts of the world

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
(Poland)

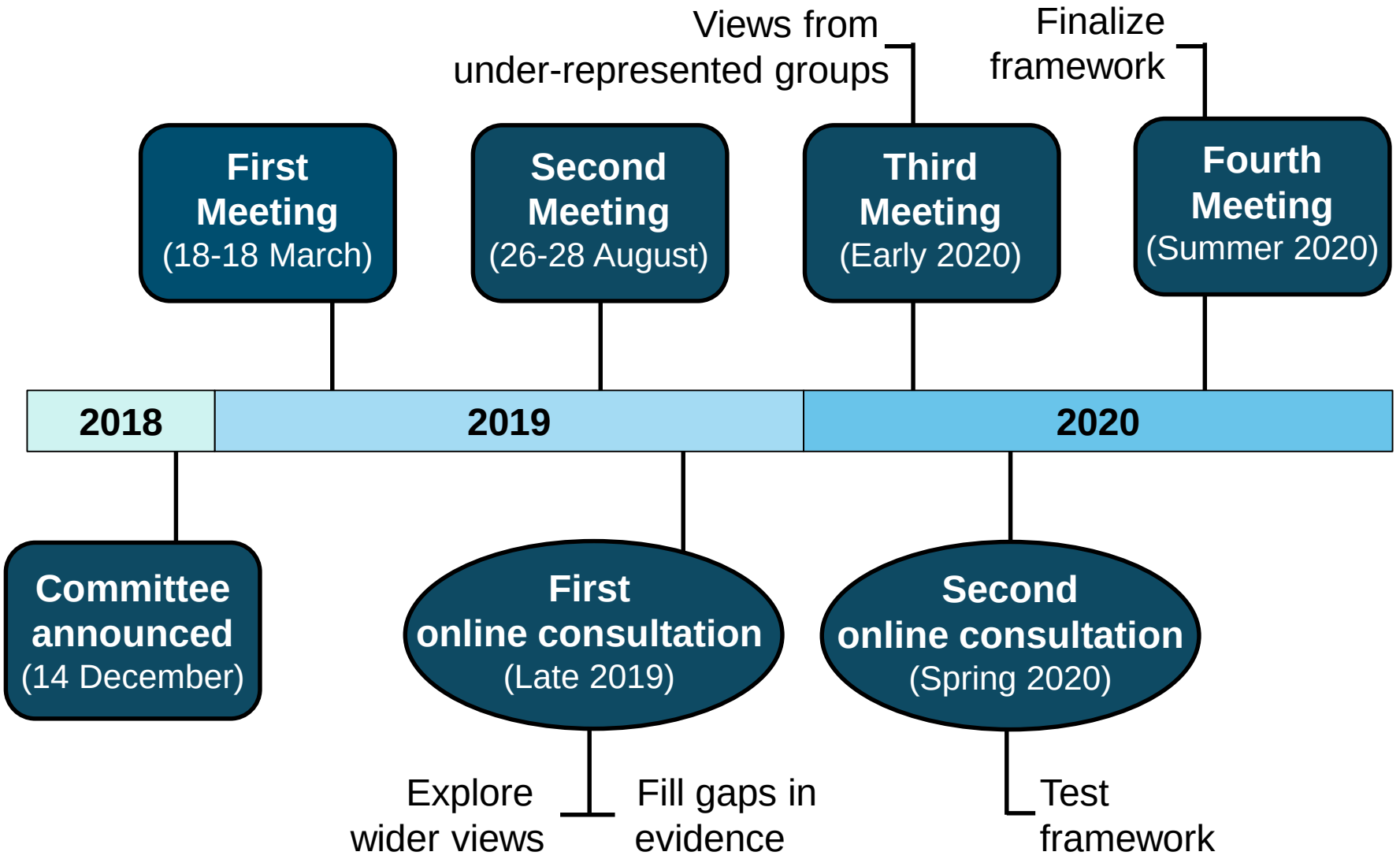
Jantina De Vries
(South Africa)

Cynthia Holland
(Australia)

Work of the Committee

https://twitter.com/who/status/1108080805182689282

Timeline


Views from under-represented groups
Finalize framework
First Meeting (18-18 March)
Second Meeting (26-28 August)
Third Meeting (Early 2020)
Fourth Meeting (Summer 2020)
2018
2019
2020
Committee announced (14 December)
First online consultation (Late 2019)
Second online consultation (Spring 2020)
Explore wider views
Fill gaps in evidence
Test framework

Working groups

1. **Registry**
   - Scope
   - Format
2. **Responsible stewardship of science**
   - 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

Responsible stewardship of science

Integrity of science & whistleblowing/Duty to report

- Need to improve the reporting of unregistered, unethical or illegal research and development activities
- Must ensure:
  - privacy protections for individuals making reports & those being reported
  - protection from retribution for those reporting
- Will require a broad community response, both:
  - Scientific community
  - Policy, regulatory and broader oversight community

Responsible stewardship of science

Risk havens/Ethics Dumping

Need to know how to prevent researchers or companies locating relevant activities in countries with weaker regulatory infrastructure for no reason other than to avoid regulation and ethics guidelines that exist in these countries

- Considerable work needed on capacity building and on standardization of regulatory and oversight regimes
- Active discussion among the bioethics community
- This will be a component of the governance framework

Statement

Clinical application of human germline genome editing

The Committee recommended to the Director-General "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

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

Registry

Recommendation from 1st meeting

…a more structured mechanism for collecting and curating details of planned and ongoing research:

- Recommended WHO established a registry of relevant research
- Failing to provide information “must be considered a fundamental violation of responsible research”
- Work with funders & publishers to encourage registration of research
- Needs to be able to include products and clinical applications in the future
- Established a working group to design architecture of repository, including:
  - Types of research to be covered
  - Metadata to be collected to describe research

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 has developed draft templates & **keywords** to gather information
- **First phase to focus on clinical applications – currently somatic**
- Subsequent work to add relevant **basic research – on embryos and germline cells** *where these will be used to create early embryos*
- Pilot registry beginning in collaboration with communities most likely to generate relevant work – on which it should not impose a regulatory burden

Governance framework

Overview

- **Principles**
- **Elements**
- **Fitting elements to specific contexts**
- **Scenarios** (*under development*)
- **Promulgation and oversight** (*under development*)

Governance framework

Principles

1. **Transparency** – sharing information on what is happening, how & why it is necessary;
2. **Inclusiveness** – drawing on the full contributions of all parts of society, thereby providing diverse points of view, skill sets & additional methods of program management & measurement;
3. **Responsible stewardship of science** - following good practice in scientific conduct, attempting to maximize potential benefits & minimize risk of harm;
4. **Fairness** - equal access to opportunities;
5. **Social justice** - celebrating & promoting diversity.

Thank you

World Health Organization

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