

# WHO Human Genome Editing Committee



World Health  
Organization

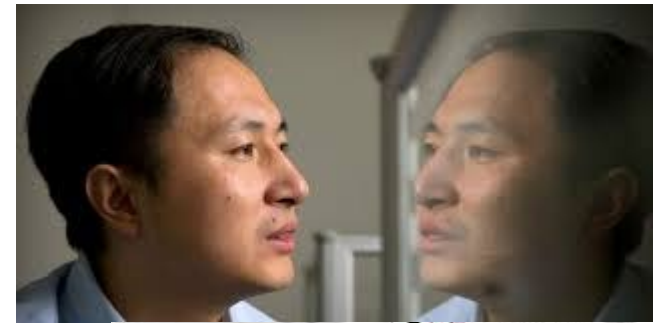
**Global Forum on Scientific Advances**

**Katherine Littler, WHO**

December 2019

# The He Jiankui Case

- The starting premise?
- Global condemnation
  - Scientifically too premature
  - But ethically contentious as well
  - Lack societal awareness, preparedness, engagement
- What does this say about status of oversight of science?



# Current Status of Governance

- Patchwork of regulations and responses
  - Regulation
    - Lack of clarity
    - Permissive vs prohibitory (real tension here)
    - Implementation & enforcement issues
    - Divergence vs ‘leap frogging’
  - Responses
    - To establish norms & harmonize regulation
    - Moratorium
- Issues of national sovereignty vs need for global response

# Governance Challenges

- Fast pace of advancements – regulatory mechanisms struggle to keep pace
  - Require ‘bottom up, community driven involvement’
- Democratization of technology
  - People with access who sit outside the traditional institutional governance structures of science & technology
  - Calls for ‘fair access’ to the technologies
  - Calls for greater inclusion in development of governance mechanisms – context matters
- Is harmonization the answer?
  - Transboundary nature of research
  - Some regional egos – NEPAD
  - Equal protections, prevents ethics dumping
  - Agreement across nations very difficult, different approaches to governance

**All equals the need for an ‘ecosystems’ approach to governance**

# Governance Challenges cont.

- The rise of engagement in global health discourse
  - How do we transition from the buzzword mentality?
  - Acknowledgement of need to include voices in the research enterprise and in the design and delivery of global health outputs
  - Tension between the information/education, engagement & empowerment functions – define why we are engaging:
    - To build trust in science? about alignment with broader societal goals? Minimizing the risks associated with implementation?
- Call for Broad Societal Consensus
  - What do we require from our ‘publics’ before we can proceed? What does this look like in different settings?
  - How does or should this fit into political decisions making?

- 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



## *Scope*

### **Both somatic and germline human genome editing**

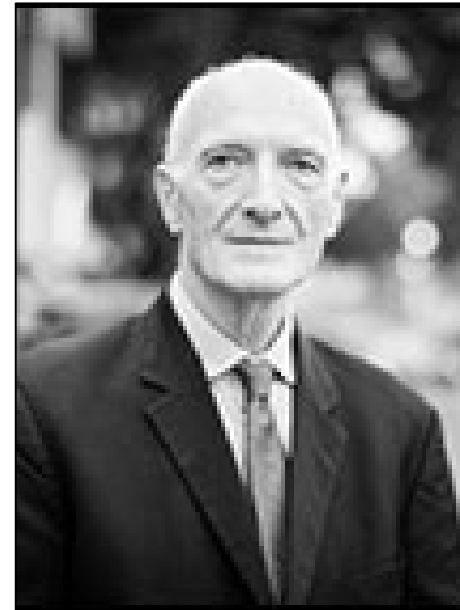
- Consensus agreement on the need to include somatic genome editing, because:
  - Trials have already begun and it has potential relevance to many individuals affected by genetic disease, cancer, etc
  - Regulatory and governance gaps
  - Concerns about inappropriate use
  - Concerns regarding rogue 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 Metz  
(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)

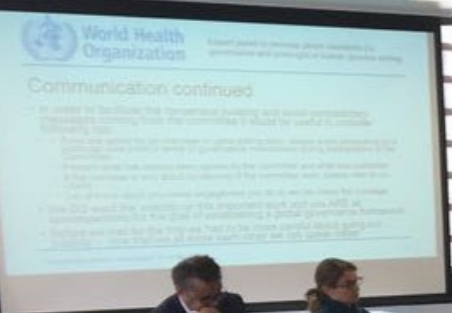


Jantina De Vries  
(South Africa)



Cynthia Holland  
(Australia)

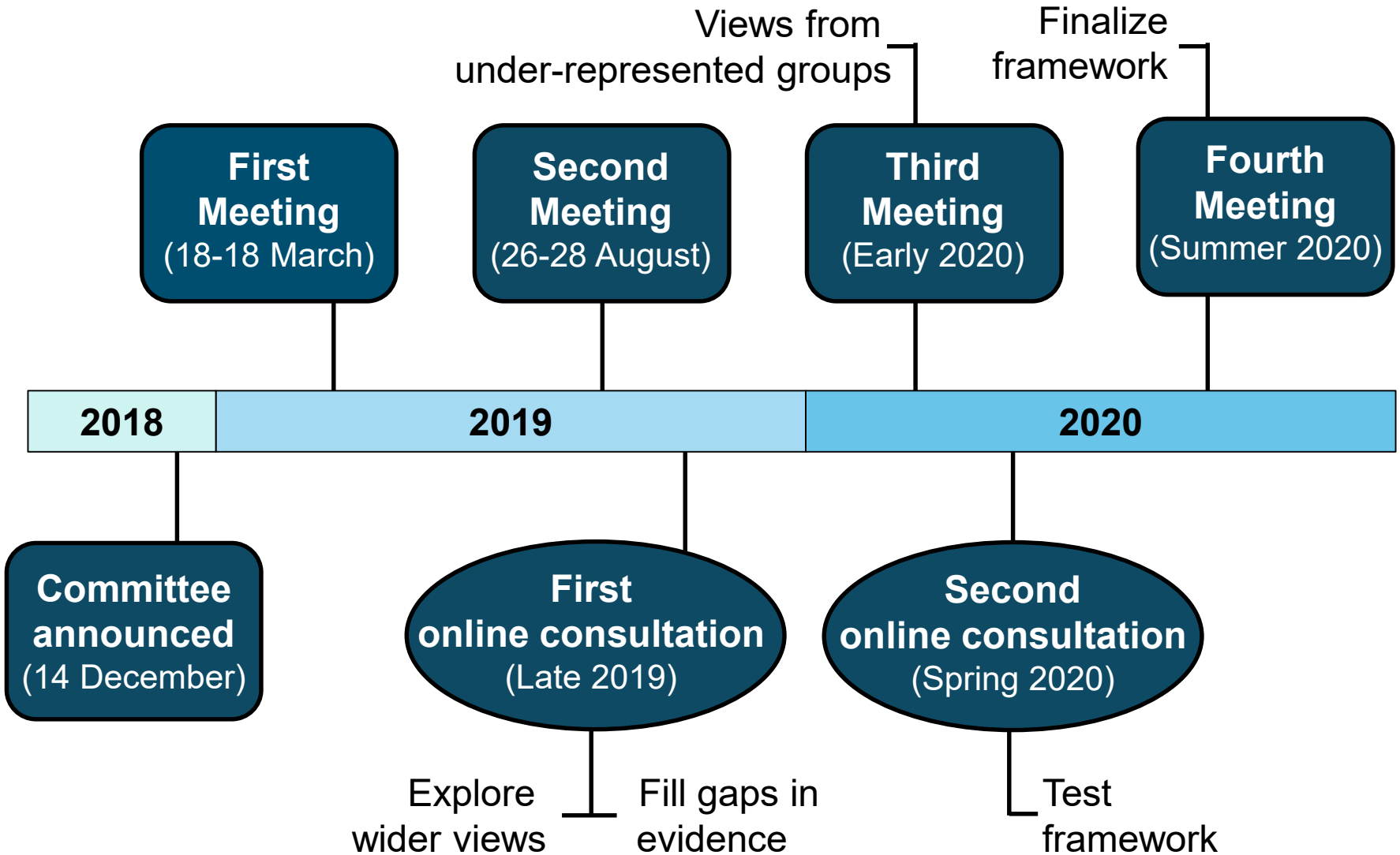




# Work of the Committee

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

# Timeline



# Working groups



## 1. Registry

- Scope
- Format

## 2. Responsible stewardship of science

- Ethics Dumping/ Risk havens
- Whistleblowing/ Duty to Report?

## 3. Oversight issues

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

## 4. Education, engagement, and empowerment

- Understanding how we need to engage
- Considering role of engagement more broadly

# 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>

# The Governance Framework Approach



**What** (issues) Differ depending on technology – i.e. acceptability of human germ line editing

**How** (mechanisms): Regulation, Codes of Conduct, Principles,

**Who** (stakeholders) Governments, regulators, funders, researchers, publics, patients groups, private sector

Need for agreed minimum standards across the framework, identified best practice

Need for 'up regulation and down regulation' of mechanisms within the framework depending on context

Need to build horizon scanning in – build anticipatory governance (related to the 'When')

# Thank you



World Health  
Organization

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