



JCG nCoV-2019 Meeting Summary

VTC

February 4, 2020

Attendees

- Peggy Hamburg (JCG Chair)
- Helen Rees (SAC Chair)

Member Institutions Represented By

- Marco Cavaleri (EMA)
- Gwen Eamer (IFRC)
- Mark Feinberg
- Marion Gruber (FDA)
- Nagwa Hasanin (UNICEF)
- Ana Maria Henao Restrepo (WHO)
- Giada Mattiuzzo (NIBSC)
- Aurelia Nguyen (GAVI)
- Els Torreele (MSF)

Working Groups Represented By

- Daniel Brasseur (Regulatory WG)
- Murray Lumpkin (Regulatory WG)

CEPI Secretariat

- Svein Rune Andersen
- Jakob Cramer
- Luc Debruyne
- Raul Gomez Roman
- Richard Hatchett
- Elen Hoeg
- Frederik Kristensen
- Paul Kristiansen
- Nicole Lurie
- Dawn O'Connell
- Shannon Quinlan
- James Robinson
- Melanie Saville
- Joseph Simmonds-Issler
- Debra Yeskey

The Joint Coordination Group met by teleconference on February 4, 2020, to discuss the current and accelerating outbreak of nCoV-2019, the role of CEPI, and the role of the JCG in responding to the outbreak.

CEPI's Current Response Posture

Richard Hatchett, CEPI's CEO, shared the work that CEPI is currently undertaking to respond to the nCoV-2019 outbreak. That work includes: the funding of four vaccine candidates and a rolling call for additional candidates. CEPI has also seconded staff to support WHO's response effort. In addition to this work, CEPI is focused on ensuring equitable access to these vaccines when they become available.

Regulatory Work by JCG Members

Marco Cavaleri (Head of Office, Anti-infectives and Vaccines in the Human Medicines Evaluation Division at the European Medicines Agency) shared that EMA is already actively working with developers on their nCoV-2019 candidates. A press release outlining their approach and an inbox for inquiries will be released very soon. Marion Gruber (Director, Office of Vaccines Research & Review at the US Food and Drug Administration) also indicated that FDA was already having high level discussions with manufacturers regarding their candidates. Both Marco and Marion emphasized the importance of having collaboration between EMA, FDA, and global regulators and the need to find the most efficient way to have technical working groups with each company. Could there be a general task force that standardizes what all developers need to achieve? A meeting with global developers is being planned for March in Brussels to discuss this and several issues. WHO and AVAREF are aware of the meeting. Chinese regulators are being invited as well.

- UNDER CONSIDERATION: How could the JCG support a task force of global regulators?

Assays and Standards

Paul Kristiansen, head of CEPI's Biological Standards and Assays Research and Development Division, updated the group regarding the work underway to develop the needed animal models, assays and standards to develop and test the nCoV-2019 vaccines. The National Institute for Biological Standards and Control (NIBSC)—a JCG member—is working with CEPI to create the needed internationally accepted standards. FDA indicated it is discussing animal model development with BARDA.

WHO Epi Update

Ana Maria Henao Restrepo, Medical Officer, Department of Immunization Vaccines and Biologicals, at the WHO, updated the group on the latest case counts in nCoV-2019 outbreak. (20,279 cases at the time of the call.) The outbreak continues to accelerate rapidly. Thus far, there are very few cases in children. The vast majority (87%) are adults.

Manufacturing Needs for Vaccines

Jim Robinson, head of CEPI's Sustainable Manufacturing Working Group, presented CEPI's strategy for managing the manufacturing needs for the nCoV-2019 vaccines. CEPI is in the process of assessing global manufacturing and fill/finish capacity and will begin identifying potential partners in the coming weeks. Bottom line: Looking for diverse and multiple locations. Will likely need plan to produce 1 billion doses if this becomes a serious global pandemic. Challenges include the fact that nCoV-2019 vaccine manufacturing will likely coincide with flu vaccine manufacturing—which will make finding capacity that much more challenging. In addition, several of the nCoV-2019 candidates are on platforms that are not currently licensed – which may slow the process down quite a bit.

- REQUEST of JCG MEMBERS: If you are aware of any manufacturing capacity that has not been already identified (Jim can confirm) please let Jim know: Jim.Robinson@cepi.net.

Mass Vaccination Campaign Needs and Challenges shared by JCG Members

Nagwa Hasanin, Senior Health Adviser at UNICEF and Aurelia Nguyen, Managing Director for Vaccines and Sustainability, weighed in on the critical needs and challenges regarding a mass vaccination campaign. Cold chain issues; challenges around investigational vaccines including informed consent and insurance; community engagement and communication strategy; special populations; coordination with infection prevention measures; as well as the need for a transparent allocation of supply were all flagged as issues to be aware of. Gwen Eamer of IFRC flagged the importance of applying lessons learned from the Ebola outbreaks.

- REQUEST of JCG MEMBERS: CEPI will reach out to many of you in short order regarding anticipated needs for a future vaccination campaign.

Conclusion

JCG agreed to stay in touch as the outbreak continues and reconvene as needed.