CEPI Joint Coordination Group (JCG) meeting summary

Date	Time	Location
Thursday 31 August, 2023	15:00-18:00 BST	Virtual

Attendees

JCG members

- **Cherry Kang**, Bill & Melinda Gates Foundation (Chair)
- **AVAREF** – Charles Shey Umaru Wiysonge, Chinwe Jaja
- **DCVMN** – Rajinder Suri
- **FDA** – David Kaslow
- **FIND** – Bill Rodriguez
- **GAVI** – Hannah Kettler (delegate for Derrick Sim)
- **IFRC** – Petra Khoury
- **MSF** – Sidney Wong, Francisco Viegas
- **UNICEF** – Andrew Owain Jones
- **Wellcome Trust** – Charlie Weller
- **WHO** – Ana Maria Henao Restrepo
- **World Bank** – Mukesh Chawla

Guests

- **CEPI SAC Chair** – Manu Hanon
- **Africa CDC** – Merawi Aaragaw, Shingai Grace Machingaidze
- **IAVI** – Mark Feinberg
- **PAHO** – Lionel Gresh (delegate for Andrea Vicari)
- **WHO** – Tim Nguyen

Apologies

- **EMA** – Marco Cavaleri
- **SEARO** – Edwin Salvador

CEPI

- Zoe Adler
- Jakob Cramer
- Sarah Doyle
- Anand Ekambaram
- Tim Endy
- Richard Hatchett
- Andrew Hebbeler
- Frederik Kristensen
- Ingrid Kromann
- Alessandro Lazdins
- Mark Lucera
- Nicole Lurie
- Oyeronke Oyebanji
- Katrin Ramsauer
- Neren Rau
- Kristine Rose
- Melanie Saville
- Joe Simmonds-Issler
- Gwen Tobert
- Saul Walker
- Claire Willman
- Holly Wingfield

From R&D to vaccine introduction: roles and responsibilities in bridging the gap

CEPI presentation

Nicole Lurie, Executive Director for Preparedness and Response at CEPI, explained that CEPI's Lassa and Chikungunya portfolios have reached advanced development stages, raising downstream questions and challenges about vaccine introduction, use, and equitable access. She therefore requested JCG advice on how/whether CEPI should engage in this space, vis à vis the roles and responsibilities of other JCG partners. She also asked for JCG thoughts on how we might apply learnings from the Lassa and Chikungunya experiences to prepare for vaccine introduction in a 100-day scenario[1] and how CEPI should think about its role in equitable access once its vaccines are licensed. Key points from the presentation include:

- Valneva is awaiting FDA authorization of its Chikungunya vaccine (expected Nov 2023) and has filed in other countries; CEPI and the EU are funding additional Phase 3 and Phase 4 studies of Chikungunya vaccines.
- CEPI is preparing with partners for Lassa late-stage trials
- There are still many evidence gaps for countries to make policy and use decisions about these vaccines.
- Equitable access is not guaranteed by licensure alone, particularly licensure in only one country.
- Approaches to country/regional engagement may vary when the pathogen is geographically limited (e.g., Lassa) vs. geographically diverse (e.g., Chikungunya, Disease X).

Key takeaways from the discussion

- There is an existing global framework for vaccine introduction and a clear desire by JCG members and CEPI itself to avoid duplication of effort. However, there was also recognition that more could be done to complement and support this framework, such as providing national, regional, and global actors with more information to aid decision-making.
- Therefore, JCG members were generally in support of CEPI generating some of the evidence for vaccine introduction, but strongly advised that CEPI cannot/should not be responsible for meeting an endless demand for evidence generation and that collaboration and coordination with other stakeholders will be key. This should extend to stakeholders outside of the JCG, and importantly include organisations who are not direct 'champions' of the vaccine in question as they may be able to provide a more objective and holistic view of country needs.
- Previous experiences including with Rotaviruses and Hib vaccines demonstrated that, even if countries are aware of the pipeline and there is a context of rising incidence, evidence alone is not sufficient to guarantee smooth introduction due to competing health priorities in-country.
- At this time, neither Chikungunya or Lassa are supported by Gavi – although future support may be possible. Gavi reviews its support for new pathogens each strategic cycle through its VIS Framework (for which Chikungunya is currently under consideration) based on standardized criteria including disease burden and risk, vaccine impact and feasibility of implementation, fit for Gavi and partners and financial implications. In between strategic cycles, as needed, Gavi uses it Living Assessment Framework to determine whether vaccines for epidemic prone diseases are suitable for Gavi support. Gavi is also exploring the possibility of co-creating, together with partners, reserves of pre-licensure vaccines for particularly bad actor pathogens – known as the Global Virtual Pooled Inventories (GVPIs).
- Specific suggestions for how CEPI could contribute to evidence generation included:
    - Helping to shape clinical trial and clinical evidence generation protocols at a global level based on understanding of regional regulatory and policymaker needs, and subsequently empowering endemic countries to continue global work at a regional level.

[1] The 100 Day Mission aims to have vaccines ready for initial authorisation and manufacturing at scale within 100 days of recognition of a pandemic pathogen, when appropriate.

- For Chikungunya, generating data on how previous infection affects long-term immunity.
- Experience of vaccine introduction to date has taught us that early partner engagement around risk communication, preparing communities, and increasing demand is critical – both in a 100-day scenario, and during interpandemic periods.

Preparing for outbreak response: inter-organizational coordination

CEPI presentation

Saul Walker, CEPI Director of Public Partnerships, updated the JCG on how CEPI, Gavi, UNICEF and WHO are working with regional and other agencies through the 'xVAX' initiative to identify and address concrete operational questions about our collective vaccine response to future outbreaks, epidemics and pandemics. This work is intended to contribute to the WHO-led interim MCM Network while political processes (the INB and the Working Group on Amendments to the International Health Regulations) are ongoing and xVAX will likely form the basis of the Network's Vaccines Working Group.

Key learnings from xVAX workshops to date include:

- Organizations have different terminology, frameworks, and sources of information for early-stage risk assessments and activities that are unfamiliar to each other.
- There is no established forum for early-stage vaccine discussions (the International Coordinating Group on Vaccine Provision plays a more specific role for selected known pathogens), as a part of a broader public health response. xVAX as part of the MCM Network could play this role.
- There are multiple surveillance, lab and research networks. Mechanisms for collaboration and information sharing in emergencies across these networks are variable.
- Vaccines are a part of, and must be integrated within, emergency responses, but there are specific steps and organisational mobilisation needed for speed, scale and equitable access.

Drawing on these learnings, Walker asked the JCG how this broader forum can work to address them, and what the role of the JCG should be in early outbreak response.

Key takeaways from the discussion

- Operational alignment and coordination at the global or even regional level is insufficient if it is not connected to plans and realities at the national level. (An example given was that in 2022, the EU offered to donate mpox vaccines to countries in Africa, but no mechanism existed for deploying or stockpiling a vaccine in an African member state in which the vaccine was not yet licensed.)
- The JCG has a unique value as an informal forum for frankly exchanging views and information between key stakeholders. It is not a decision-making body but is nonetheless an important group to feed into other fora given the quality of insights generated and its agility. Members particularly championed the role of the JCG as a convening body in the very early stages of an outbreak, at least on an interim basis until ongoing political dialogues determine the appropriate long-term solution.
- CEPI clarified that JCG members may request a convening via the Chair or CEPI Secretariat.

Preparing for outbreak response: organizational planning

CEPI presentation

CEPI has recently updated its 'core' outbreak response plan, which describes the operational framework within which CEPI will respond to an outbreak, agnostic of pathogen. The plan defines three levels of active response (in addition to steady state actions and de-escalation) and relies on streamlined governance procedures for agility and speed. Targeted response and preparedness plans for each of CEPI's priority pathogens are currently in development, and all of these plans are living

documents that are revised on a continuous basis to reflect real-time learnings and evolution in CEPI's vaccine portfolio and the broader ecosystem.

Key takeaways from the discussion

- Partners committed to sharing their thoughts on the plan offline, and it was agreed that the discussion should be continued at a future JCG meeting, possibly in the form of a scenario-based exercise. Initial suggested topics included exploring how to make decisions about appropriate trade-offs and when to begin surge financing.
- Overall, participants were appreciative of CEPI's transparency around the plan and commented that it would certainly help them in their own thinking and planning.

Next steps

- CEPI to follow-up with JCG partners for feedback on topics they would like to see included in a tabletop exercise during the next JCG meeting on 30-31 January.