

Joint Coordination Group (JCG) Meeting Summary

Date Time Location

Tuesday, 11 February 2025 13:00-16:00 GMT

Virtual

Welcome and Introductions

The JCG Chair, Gagandeep Kang, and CEPI DCEO, Aurelia Nguyen, welcomed the JCG members, and in particular thanked external guests, Minister Sabin Nsanzimana (Government of Rwanda), Wessam Mankoula (Africa CDC), Amy Finan (Sabin Vaccine Institute), Andrea Vicari (PAHO) and Wolfgang Philipp (HERA) for joining.

Aurelia reflected that, over the past year, the world has experienced a significant number of outbreaks, and ahigh number of elections, resulting in several moves away from incumbent governments; however, we are only just beginning to see the effect of these changes now, making this a prime moment for JCG partners to reflect together on system capacity, roles and connectivity.

The main objectives of this JCG meeting were to discuss:

- 1. What recent outbreaks can teach us about the 100 Days Mission, and how these learnings could be applied to future potential threats;
- 2. How thinking is evolving with regards to stockpiling and access to investigational, emergency authorised and licensed vaccines.

Recent Outbreaks and Their Lessons for the IOO Days Mission

The JCG heard brief presentations from the Government of Rwanda, Sabin, WHO, Africa CDC, UNICEF, Gavi and CEPI, outlining each organisation's involvement in, and key learnings from, the recent Marburg and Mpox outbreaks.

Marburg

Partners were greatly encouraged by the speed of the Rwanda Marburg response and took time to reflect on the 'near perfect' conditions that facilitated it. They noted that:

• The response built on years of lessons from previous outbreaks, work by WHO and the countries in the region to increase Filovirus preparedness, and the work of multi-stakeholder groups such as the WHO MARVAC (now the Filovirus Collaborative Open Research Consortium).

- As the Sabin vaccine candidate (notably, the WHO preferred product) had already entered Phase 2 trials, with sites in Kenya and Uganda:
 - the Rwandan Ministry of Health and Rwandan FDA had quick access to clinical and contextual data to help inform their decision-making
 - o regulatory documents had been prepared and a trial protocol was available for adaptation
 - 10,000 doses of investigational vaccine were ready for use, with the owner willing to donate for outbreak use, and the manufacturing partner in a position to rapidly label, ship and release them
 - An export permit from Italy to Africa was in place.
- Strong partner relationships had already been established prior to the outbreak, and response roles and responsibilities tested during a 100 Days Mission exercise hosted by CEPI with the Government of Rwanda and partners in Kigali two weeks earlier around the operational steps to rapidly develop, authorise, and administer a vaccine in response to a hypothetical public health emergency. The exercise also clarified what activities could move into the preparedness rather than response phase, and what could happen in parallel rather than sequentially.
- The Government of Rwanda demonstrated strong political will and leadership, and fostered a culture of trust and transparency, which they extended not only to partners but also to their citizens. Partners received daily updated surveillance and testing data, and vaccine trial enrolment, and were able to have open conversations about the developer's data collection expectations and priorities and to problem solve around them. This set the tone for the response and was a critical driver of success.

When considering how neighbouring countries can learn from Rwanda's experience and best prepare for future outbreaks, partners recommended focusing on: diagnostic testing, in-country lab capacity (noting that exporting samples can cause delays and introduce risk) and clinical trial preparedness. Africa CDC is already pushing this agenda within the region. Since the Marburg outbreak was declared over in December, Rwanda has increased surveillance in ICUs and is routinely running tests for a range of outbreak pathogens (e.g. Viral Haemorrhagic Fever and Ebola).

Financing of Pandemic Preparedness and Response activities is also top of mind given the current political climate, with partners noting an increased focus on a) securing sustainable domestic financing for health challenges in Africa and b) clarifying mechanisms for mobilising or accessing emergency funds e.g. Gavi's First Response Fund.

Key Takeaways from the Discussion

Trust, transparency and sharing were seen as central to the success of the Rwandan response. However, adoption of these principles during future outbreaks will be dependent on more effectively demonstrating the benefits of country transparency (i.e. ensuring countries have equitable access to any tools that result from participating in research or sharing country-level data), and avoiding unilateral decisions which have previously dented trust and discouraged transparency (e.g. regarding travel restrictions). There is also a significant amount of 'sharing' and collaboratively designed tools (e.g., protocols) that have been developed as part of preparedness efforts.

Mpox

Millions of doses of both the MVA-BN and LC16 Mpox vaccines have been donated to affected countries; however, there have been significant challenges related to acceptance and readiness.

In some cases, countries have taken multiple weeks to secure Emergency Use Approval from their National Regulatory Authorities. In others (for example, the Democratic Republic of the Congo), a mandatory charge has been applied to donated shipments which has delayed distribution. A lack of clarity on the mechanism by which countries can access doses has also led to demand being lower than

expected. MSF noted they were keen to understand from partners what they can help to convey in countries to encourage/accelerate uptake.

Investigational Reserves and Internationally-Held Stockpiles

JCG partners were asked to share how their thinking and internal efforts had progressed on the topic of investigational reserves (IRs) since it was last discussed by the group in June 2024. They were asked to reflect on learnings from recent outbreaks and to provide feedback on what they would like to see addressed within white papers due to be commissioned by CEPI. The goal of the white papers will be to 'analyse options regional and global partners could take to ensure epidemic vaccines and biologics [...] are available to countries to respond to outbreaks in the long term'.

The JCG was grateful to CEPI for bringing this topic to the table, and multiple partners expressed interest in ongoing engagement in the white paper development.

Key Takeaways from the Discussion

- Gavi continues to play a key role in stockpiling, and works closely with the WHO, UNICEF and the International Coordinating Group on Vaccine Provision (ICG) amongst others. It has recently approved the creation of two global vaccine stockpiles against Mpox and Hepatitis E, to be established once licensed vaccines are available. Gavi also recognises the increasing need for investigational reserves to control outbreaks and generate evidence to accelerate licensure.
- Geopolitical shifts are exposing the vulnerability of overreliance on parts of the ecosystem.
 Moving forward, it will be critical to ensure that stockpiles are managed and can be accessed
 by international partners. Ecosystem changes and its impact on international access to
 stockpiles are of particular concern to humanitarian organisations such as the IFRC who
 encountered challenges accessing stockpiles under COVAX, but are responsible for providing
 support to the global land not governed by standard or national health systems.
- UNICEF continues to assess the benefits of establishing licensed vaccine stockpiles, and is working with partners to try and resolve questions around liabilities and accountability.
- Questions were raised as to whether stockpiling vaccines for a handful of high-risk pathogens would be sensible, or whether thinking needs to align more with the viral families approach.
- Developers and manufacturers are keen to be part of the conversations on IRs and stockpiles.
- The JCG would like to see CEPI's white paper clearly articulate:
 - the strengths and roles of different partners in the ecosystem in mitigating risk along the value chain.
 - how decisions will be made regarding selection of an appropriate candidate in each situation, and who will be responsible for maintaining an up-to-date list of emerging candidates.
 - how different reserves can best be operationalised: where they will be stored (across single or multiple hubs?), who will be responsible for maintaining and shipping them, who will decide when and how to allocate doses, and how insurance, liability and indemnity can be managed.
 - o actions that can be taken to extend shelf life, mimise wastage and ensure financial sustainability of stockpiles.
 - o how to engage with different NRAs to ensure rapid EUL at the point of an outbreak.
 - when it might be appropriate to employ alternative approaches (e.g. rapid scale up), noting that there cannot be a one-size-fits-all solution.

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• There was also discussion on how vaccine confidence can be concurrently addressed, to ensure that vaccines are not only made available, but also reach the arms of people who need it.

CEPI 3.O Strategy Development

CEPI has recently passed the halfway point of its second five-year cycle (CEPI 2.0) and as such, is beginning to think about development of its CEPI 3.0 strategy, due to be launched in 2027.

2025 will be a critical year for engaging external stakeholders in thinking about the trajectory of the preparedness and response ecosystem, and the role that CEPI will play in it moving forward.

The JCG is a critical advisory body for CEPI, and so will have the opportunity to provide input into the draft strategy at a number of key points this year, beginning with the face-to-face meeting in May.

AOB

The next CEPI JCG meeting will take place in London from 15-16 May, 2025.

Next Steps

• JCG partners are requested to provide feedback to CEPI on topics for the upcoming meeting.

Annex I: Attendees List

JCG Members

- Cherry Kang (Chair)
- AVAREF Kwasi Nyarko (Delegate for Chinwe Iwu-Jaja)
- **DCVMN** Rajinder Suri
- **EMA** Marco Cavaleri
- **GAVI** Emanuele Capobianco (delegate for Derrick Sim)
- **IFRC** Petra Khoury

Guests

- Africa CDC Wessam Mankoula
- **HERA** Wolfgang Philipp
- **PAHO** Andrea Vicari

Apologies

- FDA David Kaslow
- FIND Ifedayo Adetifa, Sergio Carmona

- **IFPMA** Hamilton Bennett
- MSF Julien Potet (Delegate for Nathalie Ernoult)
- **UNICEF** Ann Ottosen (delegate for Andrew Owain Jones)
- Wellcome Trust Titus Divala
- WHO Scott Pendergast, Tim Nguyen, Ana Maria Henao Restrepo
- Government of Rwanda Minister Sabin Nsanzimana

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- Sabin Amy Finan
- World Bank Magnus Lindelow