CEPI SAC meeting summary

Date

Wednesday 1 November 2023

Location

Virtual

Attendees

Chairs

- **Emmanuel Hanon**, Vicebio, BE (Chair)
- **Michael King**, University of Virginia, US (Vice-Chair)
- **Laura Palomares,** Instituto de Biotecnología, Universidad Nacional Autónoma de México, MX (Vice-Chair)

SAC members

- **Alash'le Abimiku**, International Research Center of Excellence, Institute of Human Virology, NG
- ***Vincent Ahonkhai**, Gwynedd Consultancy Group, LLC, US
- **Sani Aliyu**, Cambridge University Hospitals Foundation Trust, UK
- **Vineeta Bal**, Indian Institute of Science Education and Research, Pune, IN
- **Luciana Borio**, Arch Venture Partners, US
- **Paula Bryant**, National Institute of Allergy and Infectious Diseases, National Institutes of Health, US
- ***Yunlong Cao**, Peking University, CN
- **Christian Drosten**, Charité – Universitätsmedizin Berlin, DE
- **Peter Dull**, Bill & Melinda Gates Foundation, US
- **Azra Ghani**, Imperial College London, UK
- **Rebecca Grais**, Pasteur Network, FR
- ***Glenda E. Gray**, South African Medical Research Council, ZA
- **Ken J. Ishii**, International Vaccine Design Center, The Institute of Medical Science, The University of Tokyo, JP
- ***Amine Kamen**, McGill University, CA
- **Kent Kester**, IAVI, US
- ***Gary Kobinger**, Galveston National Laboratory/Institute for Drug Discovery, University of Texas Medical Branch, US
- **Phil Krause**, WHO, US
- **Marc Lipsitch**, Harvard T.H. Chan School of Public Health, US
- **Gary Nabel**, ModeX Therapeutics, US
- **Peter Paradiso**, Paradiso Biologics Consulting, LLC, US
- **Stanley Plotkin**, University of Pennsylvania, US
- ***Marie-José Quentin-Millet**, MJQuentinMillet Consulting, FR
- **Mahmudur Rahman**, GHD|EMPHNET, BD
- **Rino Rappuoli**, Fondazione Biotecnopolo di Siena, IT
- **Ana Maria Henao Restrepo**, WHO, CH
- ***Lynda Stuart**, Institute for Protein Design, US
- **Stephen Thomas**, SUNY Upstate Medical University, US
- ***George Warimwe**, KEMRI-Wellcome Trust Research Programme, KE and University of Oxford, UK

Apologies

- ***Rick A. Bright**, Bright Global Health, US
- **George Gao**, Chinese Center for Disease Control and Prevention, CN
- **Dominique Maugeais**, RH Solutions, FR
- **Marco Safadi**, Santa Casa de Sao Paulo School of Medical Sciences, BR
- **Krishna Mohan Vadrevu**, Bharat Biotech International, IN
- **Linfa Wang**, Duke-NUS Medical School, SG

*First meeting

CEPI presenters

- **Adam Hacker**, Director and Global Head of Regulatory Affairs
- **Richard Hatchett,** CEO
- **Melanie Saville,** Executive Director, Research and Development

A number of additional CEPI staff also attended as observers.

Introduction and objectives

A three-hour virtual SAC meeting was held on Wednesday 1 November 2023. The objectives were to:

- Update the SAC on the Global Vaccine Library (GVL) concept and obtain feedback on CEPI's role.
- Consider whether and how CEPI should expand its investments in Mpox in Africa to fill R&D and manufacturing gaps for endemic disease.

This was the first meeting for the nine new SAC members who were recruited and onboarded following a call for applications in June 2023.[1]

ITEM 1: The Global vaccine library concept

Adam Hacker, Director and Global Head of Regulatory Affairs, presented CEPI's early thinking on the Global Vaccine Library. This was presented as a concept, seeking early input from the SAC to help shape the ideation phase of the project, reflecting the importance of garnering input before detailed plans and structures are created.

At present, the vaccine preparedness ecosystem is relatively fragmented: there are few incentives and mechanisms for developers to share data, information and capabilities, and no systematic approach for identifying data gaps and prioritizing R&D across pathogens with pandemic potential. This can result in duplication of effort, and extended development timelines in both preparedness and response settings.

Stakeholders within the global health space have often discussed creating information libraries to help better connect global preparedness and response activities; however, it has not yet been agreed what information should be included (antigens, platforms, assays etc), or how such a platform should be governed.

CEPI asked the SAC to provide feedback on the overall concept of the GVL, including on any challenges or risks.

Summary of key points

- The SAC explored the key problems that the GVL might address and how it could fit in and complement the existing R&D ecosystem.
- The SAC also asked CEPI management for additional information related to how such an initiative would be funded and administered in practice.
- In the short term, the SAC advised CEPI to reduce the scope, and to prioritise collating non-competitive information (e.g., epidemiology or clinical assay data) to pilot the idea.

[1] https://cepi.net/news_cepi/new-experts-appointed-to-join-cepi-scientific-advisory-committee/

ITEM 2: Mpox

During the Mpox Public Health Emergency of International Concern (PHEIC) in July 2022, the SAC convened to identify evidence gaps with regards to Mpox vaccines and align on the role that CEPI should play in filling them. In the year that has followed, CEPI has invested in R&D activities including:

- Developing assays and standards to support accurate evaluation of existing Mpox vaccines
- Partnering with BioNtech on the development of an mRNA-based Mpox vaccine, with a view to this acting as an exemplar for the virus family as part of CEPI's vaccine library strategy.

Although the PHEIC was declared over in May 2023, concern regarding outbreaks of Mpox in endemic countries remains, where Clade I disease (which has a higher case fatality rate than Clade II, which spread internationally in 2022) persists, as do gaps related to R&D and manufacturing.

As such, CEPI asked the SAC to consider whether (and how) CEPI should expand its investment in Mpox, as well as Orthopoxviruses more generally.

Discussion

- Overall, the SAC strongly endorsed CEPI's proposal to invest in Mpox to support filling R&D and manufacturing evidence gaps in LMICs.
    - They were positive about the idea of funding the development of new vaccines - noting the relatively low efficacy of existing Mpox vaccines and limited knowledge on mechanism of action - and particularly supported investigating vaccines based on mRNA, given their potential to support building manufacturing capacity in the Global South, and provide the speed for emergency response and scale for regular use.
    - In addition, they noted that Mpox trials could help to sustain the clinical trial capacity that has been established under the Lassa programme, and that Mpox's status as both an endemic and outbreak disease could help to mitigate some of the market access challenges encountered by other pathogens that CEPI supports.
- Despite their support for funding development of new vaccines, the SAC encouraged CEPI not to underestimate the time it would take to generate sufficient data to support even emergency use. As such, they recommended also thinking about how to respond to outbreaks more creatively; for example, by investigating the effectiveness of combining antivirals with existing vaccines.
- The SAC agreed that regulators are unlikely to license a new vaccine based solely on neutralising antibody data, so strongly recommended measuring cellular immune responses and establishing their relationship with efficacy. This was seen to be additionally important as efficacy studies are likely to be difficult to conduct given vaccine supply is still very limited. Use of animal models in the evaluation of next generation vaccines was also seen as important.
- The SAC suggested that conducting randomised trials during deployment could help facilitate regulatory evaluation and approval.
    - WHO, along with in-country partners, has already developed two protocols for the evaluation of Mpox vaccines: one for ring vaccination evaluation and one for randomization during deployment.
- The SAC highlighted that the Canadian Government is funding epidemiology studies in Nigeria and DRC, and the EDCTP is investing in trial sites, so it will be important to work closely with those organisations.

Summary of key points

- There is strong support for CEPI's proposal to invest in the development of new Mpox vaccines, as well as to continue generating data to help improve the profiles and manufacturing of existing Mpox vaccines.