JCG meeting summary

Sudan Ebolavirus outbreak in Uganda

Date	Time	Location
Tuesday, 18 October 2022	17:00-18:30 BST	Virtual

JCG members

- Peggy Hamburg, Chair
- **EMA** – Marco Cavaleri
- **FDA** – Peter Marks, David Kaslow
- **FIND** – Bill Rodriguez
- **GAVI** –Aurelia Nguyen, Marta Tufet
- **UNICEF** – Michaela Briedova, Jean-Pierre Amorij
- **Wellcome Trust** – Deborah King, Charlie Weller
- **WHO** – Rogerio Gaspar, Deus Mubangizi, Ana Maria Henao Restrepo, Alhassane Toure

Guests

- **Africa CDC** – Merawi Aragaw
- **Makerere University, Uganda -** Bruce Kirenga (PI)
- **Uganda MOH –** Henry Kyobe Bosa (Incident Commander)

Apologies

- **AVAREF** – Diadie Maiga
- **DCVMN**– Rajinder Suri
- **GAVI** – Sophie Mathewson
- **IFRC** – Petra Khoury, Jason Peat
- **IPMFA/Sanofi** – Isabelle Deschamps, Thomas Triomphe
- **MSF** – Sidney Wong
- **UNICEF** – Andrew Owain Jones, Ephrem Lemango, Ann Ottosen

CEPI attendees

- **Abebe Genetu Bayih,** Africa Engagement Lead
- **Tiana Carstairs,** Project Manager
- **Luc Debruyne,** Consultant
- **Bill Dowling,** Head of Preclinical Development
- **Sarah Doyle,** SAC and JCG Officer
- **Anand Ekambaram,** Executive Director, Manufacturing Network and Supply Chain
- **Adam Hacker,** Director and Global Head of Regulatory Affairs
- **Elen Høeg,** Acting Director, Policy
- **Joe Simmonds-Issler,** Chief of Staff
- **Nicole Lurie,** Executive Director, Preparedness and Response

- **Khadimul Anam Mazhar,** Scientist – Epidemiology
- **Ranna Eardley-Patel,** Sustainable Manufacturing Lead
- **Neren Rau,** Director of Policy
- **Kristine Rose,** R&D Chief of Staff
- **Alexandru Rotar,** Business Development Senior Management – Equitable Access
- **Gwen Tobert,** Emergency Response Senior Manager
- **Emma Wheatley,** Director, Access and Private Partnerships
- **Debra Yeskey,** Regulatory Policy and Intelligence Lead

Apologies

- **Richard Hatchett,** CEO
- **Frederik Kristensen,** Deputy CEO
- **Melanie Saville,** Executive Director, Research and Development

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ITEM 1: Welcome and introductions

Peggy Hamburg, Chair

Peggy Hamburg opened the meeting and outlined the objectives for the session; to ensure shared understanding of:

- the status of the ongoing SUDV outbreak in Uganda
- current and planned response activities
- challenges, gaps and potential solutions.

She welcomed all attendees, in particular Dr Bruce Kirenga of Makerere University, Uganda, the Principal Investigator for the Solidarity trial, Dr Henry Kyobe Bosa, the Incident Commander from the Ugandan Ministry of Health, and Dr Merawi Aragaw of the African CDC.

ITEM 2: Outbreak overview

Henry Kyobe Bosa, Uganda MoH

To provide context to the current outbreak, Henry Kyobe Bosa began by giving a short overview of the history of Ebola in Uganda. He noted that the first and largest outbreak (also of Sudan virus) was seen in the North of Uganda in 2000, giving rise to 425 cases and 224 deaths.

Subsequent outbreaks have been smaller and predominantly in the west of the country; however, the current outbreak is in central Uganda, in a region intersected by a major highway that spans from eastern DRC to Kampala. Due to the high connectivity of this region, there is significant concern over the risk of spread. The outbreak also follows two major lockdowns in Uganda due to COVID-19, and notable growing apathy in the community towards transmission prevention measures.

As of 18 October, there have been 61 confirmed and 20 probable cases. Over 1000 direct contacts have been identified but the contact-to-case conversion rate so far seems to be low. Nevertheless, Dr Bosa cautioned the group not to see this as the outbreak being under control, but instead to take this as a sign that cases may be being missed, or that some patients may have subclinical presentation. Uganda has initiated a targeted lockdown of the two districts that are most affected (Mubende and Kassanda).

ITEM 3: Diagnostics, therapeutics, and vaccines

Bill Rodriguez, FIND

Next, Bill Rodriguez gave an overview of current testing capacity. He highlighted that most Ebola test kits are still oriented towards the Zaire strain and, although some rapid diagnostic tests (RDTs) were developed during the 2014-16 Ebola outbreak, PCR testing remains the standard.

He noted that the four PCR Ebola testing kits that were pre-qualified by the WHO in 2014-15 have not been rescinded and so are still approved for use if required; however, there has been no active effort to maintain contact with the suppliers. As such, although the Biofire BioThreat-E does have a panel that detects SUDV, and there is a Chinese supplier that has a validated kit for SUDV, the Altona Filoscreen test is the only one currently being used for the Uganda outbreak.

In the short-term, FIND has secured funding to validate existing PCR assays for SUDV, and in the medium-term, they will be looking to support validation of existing RDT assays for SUDV.

Bill summarised that the perception is that things are under control for now in Uganda, but as there has been no effort to maintain manufacturing or safety stocks of PCR tests, there is very limited surge capacity if the outbreak expands significantly.

ITEM 4: Solidarity trial in Uganda

Ana Maria Henao Restrepo, WHO
Bruce Kirenga, Makerere University

Ana Maria Henao Restrepo then presented an overview of the Solidarity trial, a cluster-randomised ring vaccination study co-sponsored by the WHO and the Ugandan Ministry of Health which is currently being set up in Uganda and led by Dr Bruce Kirenga as Principal Investigator. This trial is designed to assess the efficacy of candidate vaccine(s) in preventing infection or severe disease in individuals who have come into direct contact with laboratory-confirmed cases of SUDV. The main secondary objective will be to assess the safety of the vaccines. There is no defined sample size for the trial as the outbreak course is, as yet, unknown. An independent vaccine prioritization committee will determine which vaccine candidate(s) are eligible for entry into the trial.

The trial design involves first identifying a confirmed case and then rapidly defining all direct contacts in order to close the ring. Individuals within the ring will then be randomly assigned to either receive immediate vaccination or vaccination delayed by 21 days. All participants are then evaluated at home at 7, 14 and 21 days and incidence rates between the two groups compared.

With regards to the status of trial preparations, Ana Maria advised that the WHO has been engaging with the vaccine developers weekly and has worked closely with Dr Kirenga on the preparation of all necessary trial documents which have already been submitted to the national regulatory authority and ethics review committee in Uganda. Dr Kirenga subsequently advised that these were due to be reviewed at 9am on 19 October. All cold chain and trial materials have been prepared and sent to Uganda from WHO stockpiles, and resources have been provided to Dr Kirenga to begin hiring permanent trial staff.

Following Ana Maria's presentation, Dr Bruce Kirenga added further detail regarding logistics, advising that a central trial base has been set up in Kampala based on the evolution of the outbreak, and a field trial base has been set up in Mubende, the epicentre of the outbreak.

He also informed the group that a communication officer is working in tandem with WHO and Ministry of Health experts on community engagement, and that, based on the excellent response rates to job adverts for trial team positions, they expect to have concluded assembling the permanent trial team within the week.

ITEM 5: CEPI activities to date

Nicole Lurie, CEPI

Nicole Lurie began by providing a brief summary of the status of vaccines against Ebola, reminding the group that there is no current approved vaccine against SUDV, and only two candidates that have completed Phase 1 trials – cAd3 made by Sabin and cAdOx1 made by Oxford. She advised that both developers have plans to progress to Phase 2 but that they currently have extremely limited numbers of vaccines vialled and ready to go, and as such, we find ourselves in a situation where ideally, we would implement a vaccine response to this outbreak, but adequate production capacity does not yet exist.

In light of this, CEPI has made a no regret decision to invest in the development of an international antibody standard to enable effective comparison of vaccine candidates, something the JCG also recommended CEPI do during the recent Monkeypox outbreak.

CEPI is also in discussion with Oxford regarding a possible non-human primate (NHP) study which may be required for the regulatory pathway (however, Ana Maria subsequently advised that the

current view of the trial committee is that this will not be required), as well as the WHO regarding possible direct support for the Solidarity trial.

Lastly, CEPI has been working directly with Sabin, Oxford and IAVI regarding acceleration of manufacturing as there are currently too few doses available of any vaccine to start a trial. Sabin has a vaccine built on a ChAd3 platform, for which there are NHP and Phase 1 data, and Oxford has a vaccine built on the ChAdOX platform, for which there are Phase 1 data. Both manufacturers have fewer than 100 doses available now. IAVI is developing a VSV-based vaccine, and is about to manufacture clinical trial material. Specifically, CEPI has focused on finding support to fill and finish vaccines – for use both in the trial, and beyond, should the vaccines be found to be efficacious. Equally, if this outbreak ends before the trial is completed, Nicole expressed CEPI's view that establishing manufacturing capacity now will still be critical to ensure that we are poised and ready with a portfolio of investigational vaccines ready to go into a trial quickly in the future.

Peggy emphasized this last point as a critical takeaway from the meeting, commenting that more and more we are realising that, in order to achieve a successful outbreak response, product development for trials is just as important as fast protocol development.

ITEM 6: End-to-end activities and needs

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In response to Peggy's invitation for other partner organisations to provide information on their own ongoing activities, Aurelia Nguyen summarised that GAVI is likely to become involved further downstream than CEPI and the WHO, focusing more on ensuring that affected and at-risk countries are able to access licensed vaccines. She advised that GAVI has already secured funding for an Ebola Zaire vaccine stockpile, but that they recognise the need to be able to address the multiplicity of Ebola outbreaks and, as such, they will look to establish a similar stockpile of SUDV vaccines in the future.

Regarding mechanisms for achieving this, Aurelia informed the group that GAVI will be investigating innovative financing models similar to the advanced purchase commitment that GAVI made for the Merck VSV vaccine in 2014, which helped to pull the vaccine through to regulatory approval and use in its investigational form during the outbreaks in DRC.

Aurelia indicaated that GAVI would seek guidance from earlier stage scientific partners on which SUDV vaccine candidates would be most appropriate to pursue.

Michaela Briedova broadly echoed Aurelia's comments, indicating that UNICEF would also be much more active further downstream, looking to be involved in developing a mechanism for sustainable supply of a licensed product. However, she did advise that UNICEF has been working closely with the WHO with regards to Ebola already in DRC as there was a recent transition to licensed products in 2021.

In response to a question about the Ugandan Ministry of Health's perspective on any outstanding gaps or challenges related to this outbreak response, Ana Maria responded on behalf of Dr Henry Kyobe Bosa who had to leave the call, commenting that it is critical to respect the MoH's preferred ways of working, ensuring that all decisions are made in collaboration with the designated WHO representative.

ITEM 7: Summary and close

Peggy Hamburg, Chair

Before closing the meeting, Nicole and Peggy reflected on the role of the JCG, and the positive impact it has had to date in providing clarity on the roles of key partners in the vaccine ecosystem, which in turn

has allowed for faster responses in outbreak situations such as this. They expressed their hope that this continued collaboration will only help to get us closer to the 100 Days Mission.