CEPI | New vaccines for a safer world

Joint Coordination Group Meeting

September 17, 2018

Washington D.C., Georgetown University

Summary of Proceedings

Attendees

Member institutions represented by

- Peggy Hamburg (Chair)
- Aurelia Nguyen (GAVI)
- Charlie Weller (Wellcome Trust)
- Dicky Akanmori (WHO/AVAREF)
- Els Torreele (MSF); Micaela Serafina for Item 3
- Emanuele Capobianco (IFRC)
- Marion Gruber (FDA)
- Mark Page (NIBSC)
- Shanelle Hall (UNICEF)

Working groups represented by

- Daniel Brasseur (Regulatory WG Chair)
- Emer Cooke (Assays WG) (by phone)

Invited

- Carleigh Krubiner, Ruth Faden, Ruth Karron – Item 6

Apologies

- EMA

CEPI Secretariat

- Carolyn Clark (VTC)
- Dawn O'Connell
- Hinta Meijerink
- Jodie Rogers
- Johan Holst
- Joseph Simmonds-Issler
- Melanie Saville
- Nadia Tornieporth (VTC)
- Nicole Lurie
- Ole Kristian Aars
- Patrick Florent (VTC)
- Per Etholm
- Rachel Grant (VTC)
- Richard Hatchett
- Richard Wilder
- Shannon Quinlan

Document Administration

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1. Opening remarks

- Peggy Hamburg (chair of the JCG), John Monahan (Senior Advisor to the President of Georgetown University) and Richard Hatchett (CEPI CEO) welcomed the JCG meeting participants.
- The JCG serves as a platform to discuss joint ownership of the products CEPI is developing, and troubleshoot challenges as they arise.

2. Updates

2.1 Standards and Assays Update

Presentation

CEPI's Standards and Assays working group shared an update regarding its Lassa request for proposals.

Comments:

- This important work should be advertised in the community at large.

2.2 Workshop on deployment of CEPI vaccine candidates in outbreak scenarios

Presentation

CEPI shared an update on a workshop it is planning on Lassa in Ghana November 8 and 9. The first day will focus on epidemiology. The second day CEPI will host discussions to seek input from the broader community regarding how it should proceed once it has early vaccine candidates that are not ready for phase 2 or phase 3 clinical trials. I.e. what are the roles and responsibilities before and during outbreaks, and what are the plans that should be put in place ahead of time?

Comments and discussion

- Defining a transparent and well-functioning governance model for decision-making around these issues will be important. CEPI is welcome to take a lead on this.
- CEPI should also consider work that is being done on ethics and regulatory pathways by African regulators. Involving them early will inform their approach and possibly streamline the process, given that they do not have full information about what is being done upstream, including on epidemiological studies. CEPI should therefore consider participating in the annual meeting of the African regulators.
- CEPI should consider doing scenario planning to assess how the size of an outbreak may affect the collection of data and its relevance towards the EUAL procedure.
- CEPI was urged to align its work with needs of affected countries and the work they are doing on research agendas.
- CEPI should consider what role it should have in "disease X". Examples include establishing operating procedures for the collection of serum.

2.3 Ebola human survivor data

Presentation

CEPI shared that it is in the process of drafting a Request for Proposals (RfP) to collect all published and unpublished data on the human immune response to Ebola and compile it into an easily accessible catalogue for use by regulators.

The FDA also presented the Drug Development Tool Qualification Program which provides a framework for regulatory acceptance of scientific tools that can aid in the development of vaccines. These exist for biomarkers, clinical outcome measures and animal models. The data gathered from CEPI's RfP may uncover a measure or marker that would qualify for this program.

2.4 Sustainable manufacturing

Presentation

CEPI shared an update on the formation of a sustainable manufacturing working group which will report to the JCG and then back to the Board in December.

Comments and discussion

- It is critical to recognise the potential conflicts between objectives; i.e. speed and costs might be working in opposing directions.
- There will not be a singular solution, but a suite of options.

3. MSF presentation

Presentation (see slides)

MSF shared their experiences and lessons learned in the recent Ebola outbreaks in DRC.

Comments and discussion

- No data is available on coverage rate for the three epidemics, but there was a substantial refusal rate.
- In CEPI's partnership agreements there are options to establish stockpiles of between 100-200 000 doses – sufficiently large enough to conduct efficacy trials and have an extra buffer if broader deployment is needed.
- There is a need to come to an agreement about the regulatory path for access to a vaccine that does not pose the substantial bottlenecks depicted in the presentation of MSF. The EUAL procedure serves as one solution, but countries themselves might choose not to use such provisions due to liability issues. Expanded access is also an option, but it must be triggered by an ask of the countries themselves. A conversation must be had with likely affected countries beforehand, and AVAREF is already facilitating such dialogues. Irrespective of the different procedures available we must keep in mind that a registered vaccine is ultimately what we are aiming for – not pushing aside the licensing issues by leaning on intermediary solutions.
- It would be important to assess different vaccination strategies to facilitate broad uptake; early vaccination of frontline health workers and community leaders might pave the way for broader acceptance. On the other hand, early vaccinations of "contacts of contacts" may curb the outbreak before a wider program is necessitated.

4. CEPI's portfolio

Presentation

CEPI presented the candidates that are currently included in its priority pathogen portfolio (CfP1) and discussed the timelines, expectations and challenges regarding their development.

Comments and discussion

- CEPI will be managing its portfolio through stage gate and portfolio review, making go/no-go decisions. An anticipation of attrition has led CEPI to invest in multiple candidates per disease.
- There is potential to ask the FDA to conduct parallel evaluations of the different candidates which would accelerate the process to determine which candidates move forward.
- On the one hand it may be easier to narrow down the scope of platforms to facilitate rapid regulatory approval, but on the other hand it is extremely difficult to predict prospectively which candidates will fail.
- In many settings there will not be enough patients upon which to test the candidates, leaving CEPI to rely on animal models as regulatory pathway.
- The decisions on prophylactic vs reactive use was determined based on target product profiles developed by the WHO, but ultimately the decision on which candidate to choose boils down to a risk assessment on their likelihood to achieve success.
- CEPI must make sure that that appropriate clinical trial sites are identified in advance and that these have the necessary capacity in place.

5. IFRC

Presentation

IFRC presented on the importance of and challenges associated with community engagement in clinical trials and outbreak response.

Comments and discussion

- Effective governments are the best entry points for creating community engagement and information platforms locally, but collaboration with relevant partners must be established in advance of the actual outbreak.
- Current ways of conducting clinical trials in affected countries are not working, and the dynamic must be changed; TPPs developed in isolation are often not suitable for outbreak settings. Local capacity must therefore be strengthened and scientists and research networks from affected countries must be involved early on to ensure applicability of clinical trial designs.

6. PREVENT

Presentation

- PREVENT presented on the findings of their recent report which advocates for the inclusion of pregnant women in clinical trials.

Comments and discussion

- There will be situations where inclusion of pregnant women is unsuitable from a risk benefit perspective, but the decision to do so must be based a proper assessment – not a default that their inclusion is unsuitable.
- In practice, “pregnant women” often means “women in childbearing age” when it comes to clinical trials, leading to a potential large exclusion.
- For each of CEPI’s three priority diseases the target product profiles speak to children and pregnant women, but it may not be feasible to include them in all projects. However, repro tox studies might be done earlier in the development process.
- More flexibility on labelling is positive, but people still tend to be overly cautious in the associated interpretation of use.

7. Open discussion

- CEPI noted that it is exploring potential areas for future funding. It was noted that capacity building will primarily be done through partners, but current budget does not allow for stand-alone investments.
- Critical to get buy-in from scientific communities of affected countries to prepare for rolling out studies during an epidemic. This is likely a whole body of work that requires an extensive effort.
- One of AVAREFs three main priorities is to address ethics regulatory readiness for outbreaks of priority pathogens. There is a strong desire for this to be an inclusive process.