Public consultation on target product profile for Nipah virus vaccine

Nipah virus is one of the pathogens in the WHO R&D Blueprint list of epidemic threats needing urgent R&D attention; it is also one of the three diseases targeted by the Coalition for Epidemic Preparedness Innovations (CEPI), which aims to develop vaccines against potential epidemics. From 1998 to 2015, more than 600 cases of Nipah virus human infections were reported. Later outbreaks, in India and Bangladesh, have caused death in 43% to 100% of infected patients. In early March, WHO published a draft Nipah virus vaccine target product profile, available for public consultation. The finalized vaccine profile will be published shortly. Nipah Vaccine TPP.

Public consultation on product profile for Lassa Fever vaccine

Lassa Fever is another disease in the WHO R&D Blueprint list of priority epidemic threats needing urgent R&D action. Like Nipah virus, it has also been selected by CEPI for the development of vaccines. WHO has published a draft Lassa Fever vaccine target product profile for preventive use, which is available for public consultation. WHO will publish the finalized Lassa Fever target product profile after taking into account comments received. Review Lassa Fever Vaccine TPP.

A Global Coordination Mechanism for R&D preparedness

28 March 2017 – Terms of reference for the Global Coordination Mechanism (GCM) for R&D preparedness were discussed at its first formal meeting in London. The primary role of the GCM is to build a consensual voluntary framework for key stakeholders to address global R&D challenges during epidemics. The second objective is to provide a high-level discussion platform and enable sharing of strategic orientations, nurturing collaborations and, addressing crucial gaps, without duplication of efforts. The GCM will meet every year and more often in case of need. Between meetings, focused working groups will address issues of common interest. The working group established in 2017 will focus on data sharing, regulatory pathways, streamlining of ethical reviews and Zika vaccine trials.
WHO publishes a detailed report on prioritization of diseases that need urgent R&D

WHO published a detailed report on the methodology used to prioritise epidemic-prone pathogens in an expert consultation in January 2017. The priority list of pathogens includes nine disease categories for which few or no medical countermeasures exist due to market failure or lack of scientific knowledge. The diseases provide the basis for work on the WHO R&D Blueprint for action against epidemics. The current list of diseases builds on the first such list published in November 2015. Detailed report available here.

Public consultation on preferred profile for epidemic vaccine manufacturing platforms

Manufacturing platforms are needed to support the development of vaccines in the event of an epidemic. The R&D Blueprint aims to provide preferred characteristics for such platforms to support funders and industry groups in making well informed decisions. The initial profile was developed by the CEPI secretariat and is being shared with their consent. WHO will publish the finalized preferred profile for epidemic vaccine manufacturing platforms after taking into account comments received. Review platform technologies Vaccine TPF.

WHO facilitates access to samples and data during outbreaks

Prompt response to an outbreak depends on the ability to move relevant samples and data from one place to another. The transfer must be simple and transparent, whilst protecting the interests of the owners. Negotiation of Material Transfer Agreements (MTAs) have proved to be challenging while an emergency is ongoing, so preparing model agreements in ‘peace time’ and raising awareness of the way they work will save time and improve the R&D response when an outbreak does occur. The R&D Blueprint held an informal consultation to facilitate more sustainable MTA negotiation. See report here.

New ethics training during health emergencies

The unpredictable nature of outbreaks sets a great challenge for clinical research and its current long lead-time methods. Researchers need guidance to ensure that, while responding rapidly to an outbreak, they respect rigorous standards for safety and best practices. The new free to access training curriculum - Clinical Research During Outbreaks (CREDO) – covers: medicine for epidemic infections, rapid appraisal, research study planning, study design, logistics and operational planning, data management, ethics, communications and engagement, special groups (children, pregnant women, mother/child), and good clinical practices. The course is now available online. For more detail, click here.

UPCOMING CONSULTATIONS

MAY 2017

- Strengthening capacity to implement adequate study designs
- WHO Informal Consultation on options to improve regulatory preparedness
to address public health emergencies

JUNE 2017

R&D Blueprint Scientific Advisory Group teleconference

Efficacy trials of ZIKV Vaccines: endpoints, trial design, site selection