Outcome document
Financing of R&D Preparedness and Response to Epidemic Emergencies
October 29-30, 2015
Oslo, Norway

Background

This Outcome document summarizes discussions that took place during the Oslo consultation on *Financing of R&D Preparedness and Response to Epidemic Emergencies* (October 29-30, 2015). It reflects views expressed and the discussion that took place, but does not necessarily reflect all interventions. Names of representatives of countries and organizations participating in the Oslo consultation on Financing can be found on the webpage of the Norwegian Institute of Public Health. Stakeholders represented included government, industry, NGOs and academia as well as charitable foundations and other relevant actors. The consultation was jointly organized by WHO and the Norwegian Institute of Public Health and hosted by the Norwegian Institute of Public Health.

The Oslo consultation is part of a response to the resolution made by WHO Member States in May 2015 (WHA68(10)) which welcomed "the development of a blueprint, in consultation with Member States and relevant stakeholders, for accelerating research and development in epidemics or health emergency situations where there are no, or insufficient, preventive, and curative solutions, taking into account other relevant work streams within WHO".

The Blueprint that is currently being developed by WHO consists of five main work streams:

- Prioritization of 5-10 pathogens and operational plan to transition from preparedness to response (Work stream 1)
- Identification of research priorities for the above priority pathogens (Work stream 2)
- Coordination of stakeholders and expansion of capacity (Work stream 3)
- Assessment of preparedness and impact of intervention (Work stream 4) and, finally,
- Exploration of funding models for R&D preparedness and response (Work stream 5).

The Oslo consultation focused on Work stream 5 and on how to ensure adequate and sustainable funding for R&D (i) preparedness and (ii) response to public health emergencies due to infectious diseases with epidemic or pandemic potential. Participants explored different options that would ensure that the required research activities are adequately financed and take place in agreement with the overall Blueprint.

Summary of discussions during the consultation

The lack of vaccines, drugs and diagnostic tests for infectious diseases with epidemic or pandemic potential is a severe threat to global public health. The Ebola Virus Disease (EVD) in West Africa has taken a devastating human toll. As of October 28 2015 there have been a total of 28,539 reported cases of EVD in Guinea, Liberia, and Sierra Leone, with 11,291 reported deaths. The EVD outbreak has also had a significant direct economic impact and continues to weaken the economies of the three hardest-hit countries with a projected $2.2 billion in lost GDP for 2015. Experiences with previous disease outbreaks (e.g. SARS) paint similar grim pictures.

There is far too little public and private investment in R&D to respond to infectious diseases with epidemic or pandemic potential. While some partners over the years have invested substantially in R&D in this area, we still fail to generate sufficient R&D investments to meet needs, in either private or public sectors. Highly uncertain demand for medical interventions has deterred investment, in particular by industry. It is difficult to predict when outbreaks may occur, which pathogen would be next, and the market case for certain diseases is largely one of mitigating future risk. Moreover, outbreaks may escalate faster in countries with weak health systems and disease control mechanisms, before becoming a threat to countries with more resources. Hence, the global R&D portfolio for epidemic emergencies has limited market-driven incentives due to the market uncertainty and limited return on investment. This combination of circumstances creates a global challenge.

Coordinated and collective action is essential to enable a robust research response to the next epidemic or pandemic, but the diverse interests of the various stakeholders and a fragmented field make coordination challenging. There is a lack of coordination of research both during preparedness and emergency response with no agreed upon unified international mechanism in this area that could: (i) facilitate the exchange of information on research gaps between funders and researchers, (ii) improve resource allocation by identifying gaps in funding or duplication of effort, and (iii) learn lessons and act on them. The Blueprint endeavors to address these gaps and improve coordination, building on the work of WHO's Global Observatory on Health Research and Development scheduled to launch in 2016, the Global Collaboration for

Infectious Diseases Preparedness Research (GLoPID-R), the Pandemic Influenza Preparedness Framework agreed in 2011 and other relevant mechanisms[1].

A better system for R&D preparedness and response is necessary to protect people in all countries. It is imperative for all countries to contribute, whether high-, middle- or low-income to both protecting their own populations as well as populations in other countries. There is a need to pay particular attention to the needs of vulnerable populations since they are prone to higher risks and have less means to prepare and respond to crises. The challenge is a health security, a public health and a development issue. It must be met by a holistic governmental response by relevant ministries, including foreign affairs, security, science & technology, health and development, and build on the involvement of both public agencies and institutions, private sector and civil society.

The participants of the Oslo consultation differentiated between the various R&D emergency and preparedness stages and the following division was considered useful:

A. The general "ecosystem" of R&D for infectious diseases, both basic and applied research
B. R&D preparedness focused on identified priority pathogens/diseases
C. Implement pre-approved protocols for clinical trials, data collection, stand-by partnerships etc. in emergencies
D. Reactive R&D tailored to the situation as a part of the response during an outbreak

The WHO R&D Blueprint is covering B, C and D while A is outside the scope of the Blueprint.

Meeting outcomes

Participants agreed that all stakeholders have a shared responsibility to ensure better R&D preparedness and response. Major stakeholders include key research institutions (such as research organizations, pharmaceutical and biotechnology companies, universities, product development partnerships) and key funders (such as government health and research ministries, government research organizations, government development agencies, other government ministries, private foundations, philanthropic organizations, and pharmaceutical and biotechnology companies).

It was proposed that all involved stakeholders collectively should aim to:

(i) increase their overall investment in R&D for emergency preparedness,

[1] See Background document to the Oslo consultation for further information on the WHO Blueprint, WHO's Global Observatory on Health Research and Development and GLoPID-R.

(ii) align their different R&D efforts to address the global priorities identified in the R&D Blueprint under preparation as well as other ongoing processes, and

(iii) ensure efficient use of existing funding mechanisms by avoiding duplication of efforts.

The Oslo consultation on *Financing of R&D preparedness and response to epidemic emergencies* identified the following to be strongly considered:

1. WHO should fulfil its mandate as the normative and coordinating authority in supporting rational and transparent identification of R&D needs and gaps for infectious diseases with epidemic or pandemic potential.

2. The WHO Global Observatory on Health Research and Development (R&D) should facilitate information sharing with a view to contribute to the identification of gaps and opportunities for health R&D and to provide information necessary when defining priorities and potential target product profiles for new R&D investments based on public health needs.

3. Better coordination among R&D stakeholders, in particular during an emergency should be achieved through identification of a mechanism which could facilitate real-time sharing of information regarding which R&D activities are already ongoing, or planned and funded. The Global Research Collaboration for Infectious Disease Preparedness (GloPID-R) network might provide a platform for such coordination amongst funders of R&D.

4. A new global mechanism would be instrumental in leveraging new and existing financing and structures for R&D preparedness and response. The mechanism would include a financing facility and a coordination function, and also provide incentives for existing funders to better coordinate their efforts. The mechanism with its financing facility could be hosted in an existing entity or a new one if no entity fulfills the recommended criteria and would focus on stages B and D in the categorization above.

5. Selection of the host entity for such a new mechanism would be based on criteria such as:
    a. Absorptive capacity (capacity to manage and disburse a large amount of funds, i.e. several hundred million USD annually)
    b. Technical and scientific capabilities to coordinate funding application and approval process
    c. Governance structure that allows for strong leadership
    d. Political and cultural acceptability for WHO member states and non-state actors
    e. Independence and neutrality

f. Flexible
g. Transparent and good governance
h. Trusted by those contributing to the financing facility
i. Inclusive of all actors (state and non-state)
j. Potential for sustainable finance over a long period in time to offer long term predictability to innovators
k. Governance arrangements built on existing, effective models, with WHO as part of the governance structure.

6. The financing facility should offer long term predictability to innovators. Strong and stable funding spurs innovation.

7. The global mechanism would finance and coordinate the R&D specifically targeting the epidemic preparedness activities and the "surge R&D" during unexpected outbreaks. This corresponds to stages B, C and D in the abovementioned division. Stage A would be covered by all R&D funders.

8. Research priorities would be related to the need for effective technologies, i.e. vaccines, treatments and diagnostics, but would also include all relevant areas of research including epidemiology, evaluating interventions and relevant social science, particularly during the "response mode" of an emergency (stage D).

9. Reliable performance metrics need to be developed to justify investment in R&D and help improve efficiency in the use of scarce resources.

10. Low- and middle-income countries should be strongly involved in all actions towards better preparedness and be invited to contribute including through funds, as the risk for future epidemics is shared among all countries.

11. Innovative financing can help to boost health R&D. Instruments for market shaping should be considered, building on the experiences from the Clinton Health Access Initiative, GAVI, UNITAID and others. Pull funding, such as stockpiling commitments, is likewise worth consideration.

12. Partnerships and alliances with animal health research communities should be formed recognizing the zoonotic relevance of potential future epidemics or pandemics, and the importance of tackling these diseases in animals before they pass to humans.

The Oslo consultation concluded that adequate and sustainable investment and new incentives are urgently needed to ensure appropriate funding for R&D preparedness and response. There is a window of opportunity to increase investment in and coordination of R&D preparedness and response, thanks to the current worldwide awareness of the threat of highly infectious pathogens. Experience shows that it is important to seize this opportunity and to start quickly with a focused objective through

defining target product profiles (TPPs) for five to ten pathogens, where no or few products currently exist, and to seek to ensure sustainable financing starting with those stakeholders that are ready to move. This requires high level political commitment to kick-start the process which would likely motivate others to join. The presentation of the Blueprint in May 2016 will provide an opportunity to act.