

Options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers

Report by the Secretariat

1. The Executive Board at its 138th session noted an earlier version of this report.¹ The present version of the report has been updated to take account of the recent outbreak of Zika virus.

BACKGROUND

2. In resolution EBSS3.R1, adopted in January 2015 by the Executive Board at its special session on the Ebola emergency,² the Director-General was requested to provide to the Executive Board at its 138th session options for strengthening information sharing and for enhancing WHO's capacity to facilitate access to diagnostic, preventive and therapeutic products, including the establishment of a global database, starting with haemorrhagic fevers. This report has been prepared in response to that request.

STRENGTHENING INFORMATION SHARING ON DIAGNOSTIC, PREVENTIVE AND THERAPEUTIC PRODUCTS, INCLUDING THE ESTABLISHMENT OF A GLOBAL DATABASE, STARTING WITH HAEMORRHAGIC FEVERS

3. A review of existing WHO databases on research and development for diagnostic, preventive and therapeutic products, such as the database on the malaria vaccine pipeline,³ and of their relationship with WHO's Global Observatory on Health Research and Development,⁴ was conducted

¹ See document EB138/28 and the summary records of the Executive Board at its 138th session, third meeting, section 1 (EB138/2016/REC/2).

² See document EBSS/3/2015/REC/1, resolution EBSS3.R1. Ebola: ending the current outbreak, strengthening global preparedness and ensuring WHO's capacity to prepare for and respond to future large-scale outbreaks and emergencies with health consequences.

³ See http://www.who.int/immunization/research/development/Rainbow_tables/en/, accessed 4 March 2016.

⁴ The objectives of the Observatory are described in resolution WHA66/22 (2013). Further information is available at <http://www.who.int/research-observatory/en/>, accessed 4 March 2016.

to identify the most suitable mechanism that could be replicated, used or expanded to strengthen information sharing and establish a global database, starting with haemorrhagic fevers. The review was based on the premise that any such mechanism would have to:

- (a) allow for the review and collection of relevant information from various heterogeneous sources and make this information available in a user-friendly, consistent and analysable format;
- (b) coordinate, conduct and collate analyses of this information to facilitate information use and agenda-setting;
- (c) include a capacity-strengthening component, enabling for example the sharing of tools and methods to allow the same data collection and analysis techniques to be used across different countries and regions;
- (d) operate on the basis of an open-access policy.

This review pointed to the potential value of the Global Observatory on Health Research and Development for filling the proposed mandate.

Global Observatory on Health Research and Development

4. The establishment of a Global Observatory on Health Research and Development was mandated by the Health Assembly in resolution WHA66.22 (2013), “in order to monitor and analyse relevant information on health research and development, building on national and regional observatories (or equivalent functions) and existing global data collection mechanisms, with a view to contributing to the identification of gaps and opportunities for health research and development”, especially for diseases that disproportionately affect developing countries, particularly the poor.

5. The objective of the Observatory is to create an online platform to:

- (a) collate, monitor and report on financial flows for global health research and development;
- (b) integrate information on financial flows for research and development with information on product pipelines and other resources that support innovation and access to medical technologies;
- (c) provide information, generate reports and allow for analyses to be carried out to inform policy-makers, donors and researchers, with a special focus on low- and middle-income countries and global health; and, in doing so;
- (d) support capacity strengthening at the regional and national levels in the governance of health research and development and innovation for improved access.

6. Phase 1 of the Observatory platform was launched in January 2016. The platform includes data on funding for health research and development, products in the pipeline for various diseases, clinical trials and research publications. In the subsequent phases, the Observatory’s functions and remit will continue to be broadened, as it receives additional resources, data and analyses.

7. While there are several comprehensive disease-specific research and development databases that facilitate information sharing in their respective areas, the goals and objectives of the Observatory

make it the most suitable option for hosting such a global database and for meeting the associated information-sharing and capacity-building needs. The reasons for this are set out below.

8. **It has experience in collecting and reporting research and development data.** The Observatory is already investing in finding solutions to common problems in the sharing of research and development data, such as inconsistencies in what is reported and how information is conveyed, and in terminologies and methods of data collection. Accordingly, it is collaborating with various partners and employing cutting-edge knowledge and information technology to resolve these common problems in an automated and efficient way. It is also contributing to capacity building in this area by sharing knowledge and tools and facilitating the development of norms and guidelines for future data collection and sharing.

9. In cases where data do not exist, work to establish primary data collection mechanisms could be organized with the support of disease experts from within the WHO Secretariat and outside.

10. **It is an existing and established mechanism.** The establishment of the Observatory entailed a significant amount of background work, the development of partnerships and the building of infrastructure and systems. It would make sense to build on and learn from what already exists.

11. **It enables all health research and development data to be stored in a single place in a uniform format.** Using the existing Observatory platform to strengthen and facilitate the sharing of information on haemorrhagic and other diseases will facilitate global efforts for data analysis and comparisons, and pave the way for more coordinated approaches to priority-setting for health research and development.

ENHANCING WHO'S CAPACITY TO FACILITATE ACCESS TO DIAGNOSTIC, PREVENTIVE AND THERAPEUTIC PRODUCTS FOR INFECTIOUS DISEASES THAT MAY CAUSE PUBLIC HEALTH EMERGENCIES

12. At the start of the outbreak of Ebola virus disease in West Africa, there were limited options available for diagnostics and disease interventions, and knowledge of the disease was limited. Furthermore, while some candidate medical products existed, they needed to undergo several more months of development before they would be ready for human trials. In addition, no framework existed for carrying out research and development activities in the event of an epidemic. The research and development efforts led by WHO in this context showed that research and development could be accelerated during an epidemic, and a precedent was set for expanded work in this area.

13. In response to resolution EBSS3.R1 (2015), WHO started work, in June 2015, on the development of a blueprint for research and development preparedness and rapid research response during future public health emergencies due to highly infectious pathogens, to address the need for increased global security against both known and emerging pathogens of epidemic potential. The objective of the blueprint is to develop options to accelerate the testing and increase the availability of medical countermeasures during outbreaks by: identifying priority infectious disease threats and research and development gaps and priorities; improving collaboration between stakeholders; and promoting an enabling environment for the conduct of research and development during outbreaks.

14. The blueprint is being developed in collaboration with experts from all relevant disciplines, convened by WHO and guided by a scientific advisory group. The first face-to-face meeting of the group was held on 24 September 2015.

15. The following paragraphs provide an overview of the different activities that will be carried out for the purposes of the blueprint, the planned workflow and milestones reached to date. Essentially, the blueprint will be developed through activities in five different workstreams, as described below.

Prioritization of pathogens and development of an operational plan

16. The knowledge and research gaps on severe emerging infectious diseases are extensive. In order to use available resources effectively, it will be necessary to prioritize some diseases for immediate attention by the global community. A list of the five to 10 most severe emerging diseases with the potential to cause a public health emergency has been identified, on the basis of the outcomes of a technical consultation held on 20 November 2015. The list will be regularly updated.

Research and development preparedness: gap analysis and identification of research priorities

17. Far from being two distinct concepts, research and development preparedness and research and development response form a continuum, so there is a need to determine what the process of transition from preparedness to response entails. An operational plan will be developed by the Secretariat, with the support of a panel of experts, for the process of transition from outbreak-readiness to action. The plan will include a separate module for each pathogen and efforts will be focused on where there may be commonalities between the diseases.

18. Research and technology platforms for epidemic-prone diseases mainly affecting low- and middle-income countries are few in number. One pharmaceutical manufacturer has offered to provide a platform to support the development of new vaccines against highly pathogenic infectious diseases. To complement this first proposal, WHO organized a public consultation in October 2015, calling for further contributions and suggestions with regard to complementary platforms from representatives of industry, product development partners and other stakeholders. In the absence of market-driven research and development activities, platforms for technology sharing could strengthen research and development efforts for epidemic-prone diseases in low- and middle-income countries.

19. The blueprint will identify the current research and development status and gaps for the five to 10 epidemic-prone diseases prioritized under the first workstream, in order to highlight which important research questions should be addressed urgently and promote the development and availability of appropriate diagnostic tools and the creation of a portfolio of promising treatments and vaccines for completion of phase 1 clinical trials in humans. This will facilitate, in the event of an emergency, the immediate initiation of advanced, large-scale and efficient clinical trials and the timely deployment of effective health technologies. Technical consultations were held on pre-clinical research, in collaboration with the United States Department of Health and Human Services, from 20 to 23 October 2015, and on clinical research, in collaboration with the Wellcome Trust, on 20 October 2015. These meetings identified the primary needs of and the next steps to be taken in each of the respective areas.

20. Middle East respiratory syndrome coronavirus was used as a model for the development of a list of research questions and a pipeline of promising medical technologies. On 10 December 2015, WHO brought together scientists, regulators, public health leaders, funders and industry representatives to review the product development landscape for Middle East respiratory syndrome coronavirus and prepare a technology road map, with a view to facilitating the coordination of ongoing research and development activities. Targeted, open and collaborative research will promote faster outcomes, more efficient use of resources and more effective implementation of outcomes.

21. On 1 February 2016, the Emergency Committee convened by the Director-General under the International Health Regulations (2005) advised that the recent cluster of microcephaly cases and other neurologic disorders reported in Brazil, following a similar cluster in French Polynesia in 2014, constitutes a public health emergency of international concern. Since then, WHO has used the framework of the blueprint to organize a research and development response, looking in particular at medical interventions targeting Zika virus.

Organization, coordination of stakeholders and strengthening of capacities

22. While the international community's pioneering work to develop medical countermeasures against Ebola virus disease in 2014–2015 has demonstrated that research and development can be accelerated, other aspects of that work point to a number of important gaps in current research and development governance, coordination and practice. These gaps must be addressed so that, next time, faster and more effective action can be taken.

23. Establishing frameworks for research oversight at the national level will enable countries to better manage research activities and data gathering on the ground.

24. The blueprint will propose a global coordination and communication framework for research on highly infectious diseases associated with potential outbreaks. Such a framework will help limit the unnecessary duplication of research, make it possible to prioritize how resources are used and facilitate the sharing of up-to-date information in a timely way, so as to maximize its impact.

25. Furthermore, the blueprint will address challenges encountered when conducting research during an outbreak, including with regard to the selection of the most appropriate study designs and the identification of best practices for engaging with communities that may have limited understanding of research processes. In addition, networks and guidance materials to support better communication and more focused use of resources, generic templates and best practice guidelines will be proposed for the implementation of research, for the establishment of legal agreements, for the timely sharing of gathered data and analyses, and for the ethical sharing of biological samples. Consultations have already been held on biobanking (5 and 6 August 2015) and data sharing (1 and 2 September 2015).

Assessment of research and development preparedness levels and the impact of interventions

26. The Ebola emergency in West Africa and the efforts being made to develop safe and effective vaccines for this disease have provided an opportunity to analyse precious information regarding important milestones, the required deliverables, acceptable timelines and achievable targets. All this information will serve as a basis for the evaluation of the outcomes of the research and development blueprint efforts. Emphasis will be placed on developing an enabling environment that will make research and development preparedness possible and on the impact that the research and development plans will have in terms of fostering a better understanding of the disease and increasing the availability of medical technologies for the next outbreak or epidemic.

27. These efforts will be maintained through the combination of a performance monitoring mechanism and a high-level checklist to assess research and development preparedness.

Funding options for research and development preparedness and emergency response

28. Ensuring that appropriate resources are assigned to both research and development preparedness and research and development emergency response activities will require the mobilization of new funding. A consultation organized in collaboration with the Norwegian Institute for Public Health in Oslo, on 29 and 30 October 2015, started work on defining which funding models – whether existing, adapted or new – might be suited to fulfilling the requirements of the research and development blueprint.

ACTION BY THE HEALTH ASSEMBLY

29. The Health Assembly is invited to note the report.

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