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BACKGROUND PAPER FOR 2014 REGIONAL COMMITTEES UPDATE ON 2014 EBOLA OUTBREAK (15 September 2014)

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CONTEXT

- The 2014 Ebola Virus Disease (EVD, or "Ebola") outbreak is the largest and most complex Ebola outbreak on record, with an unprecedented number of affected countries (5 countries as of 14 September 2015), thousands of cases and deaths¹ in the general population, and hundreds of infected health care workers.
- The outbreak continues to escalate in alarming ways, with widespread and intense
 transmission in the affected countries devastating families and communities, compromising
 essential civic and health services, further weakening economies, and isolating affected
 populations. The outbreak is aggravating fragile social, political and economic conditions in
 the sub-region.
- 3. On 8 August 2014, the Director-General, further to the advice of the Emergency Committee convened under the International Health Regulations (2005) [IHR (2005), declared the EVD outbreak a Public Health Emergency of International Concern (PHEIC) and issued Temporary Recommendations to prevent further international spread.² The Temporary Recommendations emphasize that the travel of all EVD cases and contacts should be restricted but there should be no general ban on international travel or trade; all States should be prepared to detect, investigate, and manage EVD cases.
- 4. A number of factors contribute to the propagation of this outbreak: inadequate coverage of affected populations with standard EVD control measures due to limited capacities and infrastructure; limited community engagement in prevention and control measures due to a combination of misinformation, traditional practices and cultural beliefs; the vast geographical extent of the EVD outbreak; extensive population movements for commercial and social activities across porous border areas; and severe shortages of human, financial, operational and logistic resources.

RESPONSE EFFORTS

- 5. WHO has been working closely with national authorities and a broad range of national and international partners in all affected countries to implement standard and in the worst-affected countries complementary EVD control measures. WHO has established a 4-level operational structure to coordinate this response, comprised of WHO's district-level field operations, Country Offices, the African Regional Office, WHO Headquarters; WHO has established an emergency operations coordination centre in Conakry, Guinea. UN common operational support platforms at national, regional and global levels are coordinating the receipt and allocation of strategic resourcing and in-kind contributions from governments and partners towards the implementation of mission critical response actions.
- 6. On 28 August 2014 WHO released the Ebola Response Roadmap³ with a goal of stopping the EVD transmission in 6-9 months and preventing international spread. The Roadmap outlines a consolidated approach to guide the response and priority actions for countries with widespread and intense transmission, countries with localized transmission, and preparedness activities for all countries. Implementation of standard Ebola control measures (case finding and contract tracing, case management, safe burials, social mobilization) remains the centrepiece of the outbreak response strategy, with

http://www.who.int/mediacentre/news/statements/2014/ebola-20140808/en/

¹ Situations Reports: http://www.who.int/csr/disease/ebola/situation-reports/en/

 $^{^{\}rm 2}$ WHO Statement on the Meeting of the International Health Regulations Emergency Committee:

³ Ebola Response Roadmap: http://www.who.int/csr/resources/publications/ebola/response-roadmap/en/

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complementary approaches being implemented through heightened community engagement in areas of intense transmission.

- 7. The Ebola Response Roadmap also presents a consolidated view of the estimated global resources required over the next six months by national governments, WHO, and other partners to stop the ongoing outbreak. This requirement will continue to evolve in concert with the changing state of the outbreak. There is a significant funding gap for both the consolidated resource needs and the WHO crisis management and coordination component of the budget, severely impeding the ability of WHO and international partners to adequately and effectively address this outbreak in the manner and at the scale required.
- 8. A massively scaled and coordinated international response is needed to support affected and at-risk countries in intensifying their EVD response activities and strengthening national capacities. The risk of international spread requires immediate measures to strengthen the preparedness capacity in all countries to stop transmission of an importation at the earliest stage possible. The current focus of WHO is on coordinating the scale-up of the national and international response, through its in-country and field presence and international advocacy for additional financial, material and human resources.

EXPERIMENTAL THERAPIES and VACCINES

- 9. An additional component of the Ebola Response Roadmap relates to the issues of access to specific effective therapeutic and preventive medical interventions for EVD. Although a few candidate Ebola vaccines and therapies have shown promising results in laboratory and animal models, they have not yet undergone appropriate and rigorous clinical evaluation for safety and efficacy in humans, and are not licensed for use by national regulatory authorities. The escalating scale and mortality of the outbreak, and intense attention in recent public discourse, has reinforced the urgent demand for the accelerated development and availability these compounds to support, and potentially re-orient, ongoing response efforts.
- 10. Two key considerations underpin this discussion: (i) the ethical implications of using experimental therapies, especially in vulnerable populations; and (ii) the scarcity of information of safety and efficacy in humans as well as actual lack of availability of experimental Ebola-specific therapeutic interventions in meaningful quantities.
- 11. Recent expert consultations convened by WHO examined these and other related considerations, and concluded that given the particular circumstances of this outbreak, the experimental nature of Ebola therapies and interventions should not preclude their use, in settings that would allow the evaluation of their safety and efficacy. A subsequent expert consultation identified several medical products that should be the focus of priority clinical evaluation at this time, including vaccines, blood-derived therapies, and other novel therapies. Considerations to guide examination of their prospective value for use in affected populations include evidence of efficacy in animal models, existence of satisfactory safety information as well as product availability in the short and medium term.
- 12. EVD vaccines appear to offer the most promise in the near-term, with the results of Phase 1 trials for safety and immunogenicity of two products potentially available by end-2014. Such products could potentially be used on an accelerated basis in 2015 for front-line responders such as health care workers. Therapies using whole blood or sera from EVD survivors have

⁴ Ebola Response Roadmap Web Portal: https://extranet.who.int/ebola/#

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also been prioritized for further evaluation. There are limited prospects for large-scale use of new therapeutic drugs, including monoclonal antibodies, in the near-term given the time required to scale up production. However, the safety and efficacy of selected products will continue to be evaluated through standardized protocols in treatment centres.

13. WHO will continue to provide guidance for evaluating the safety and efficacy of new EVD therapies and to work with all stakeholders to accelerate the further development, clinical evaluation and deployment of promising experimental interventions.