



SUMMARY REPORT

First Workshop of the Partners Group on Ebola Vaccines Deployment

24-26 February 2015, Geneva, Switzerland

Rev. 1

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Executive Summary

A first workshop of partners, convened by the World Health Organization, was held on 24-26 February 2015, to pursue planning and preparation goals for Ebola vaccines deployment, while convening country representatives and partners to ensure coordinated efforts in support to affected countries. The most advanced Ebola vaccine candidates are now entering Phase 3 safety and efficacy clinical trials. Depending on the evolution of the epidemic, results from clinical trials and availability of vaccines, vaccination strategies will be considered as part of the measures to control the outbreak, with a range of approaches.

The workshop contributed to address requests formulated by the WHO Executive Board during their special session on Ebola, 26 January 2015 and offered the Ebola Vaccines Deployment Team of Partners (Steering Group and three Working Groups: a. Country Implementation; b. Monitoring, Surveillance and Impact Evaluation; and c. Vaccine Supply, Allocation and Procurement) the perfect forum to: 1) finalize the collaborative framework for the deployment of Ebola vaccines and reach agreement on the next steps; 2) review progress and evidence from Ebola vaccines development; 3) review options and strategies for deployment of Ebola vaccines, within the context of the epidemiological situation; 4) develop a draft outline of a collaborative plan for the deployment of Ebola vaccines; 5) develop draft checklists to guide the country assessments and to support country readiness for the roll-out of the vaccine; and 6) review critical actions for a successful vaccine deployment, within the context of the community engagement and risk communication needs.

Emphasis was made on the importance to ensure a clear communication with experts involved in vaccine trials and on community engagement. Critical expectations from countries for vaccine deployment were presented, together with a summary of the current accelerated Ebola vaccine development, the Ebola virus disease epidemiology in West Africa and the implications for vaccine deployment strategies. Country representatives from Sierra Leone and Liberia, and a renowned anthropologist based in Guinea discussed community engagement, social mobilization in support of Ebola vaccine trials, successful introduction and risk communication within each specificity of in-country reality. Numerous challenges emerged from the discussions, such as the difficulty to identify one specific communication channel; the availability of experienced and skilled health care workers; and the mistrust from the communities. The country representatives identified several lessons learned as the importance to: train health care workers on how they should engage with communities; ensure the respect for the deceased; avoid conflicting messages; identify cultural approaches; engage with national councils, the elderly, religious leaders and community representatives. The unpredictable and hypothetical environment calls for flexibility from all partners. Although extremely challenging, this body of work presents an opportunity to have plans in place for use not only during this outbreak, but for future outbreaks. Country ownership and engagement from the onset is critical and will be prioritized, as well as communication among partners and countries, with rapid sharing and analysis of findings. It is important to learn from current experience with the vaccines during the clinical trials and to plan vaccine implementation without compromising the routine immunization programme, whilst always integrating community engagement plan into activities.

Introduction

Depending on the evolution of the current epidemic of Ebola virus disease (EVD), results from clinical trials and availability of vaccines, vaccination strategies will be considered as part of the measures to control the outbreak, with a range of approaches.

This meeting was intended to pursue planning and preparation goals for Ebola vaccines deployment, convening country representatives and partners to ensure coordinated efforts in support to affected countries.

Welcome and opening remarks

Marie-Paule Kieny, Assistant Director General, Health Systems and Innovation, WHO/HQ Geneva

This workshop will complement and build into the work that has been accomplished to date, in terms of accelerating the development of Ebola vaccines, projecting scenarios for implementation of vaccinations and securing finances to support the effort. A series of high-level meetings have offered invaluable opportunities for experts and partners to discuss and coordinate these efforts. The most advanced Ebola vaccine candidates are now entering Phase 3 safety and efficacy clinical trials and could be available for deployment in a few months, after regulatory clearance and policy recommendation.

During this workshop, available evidence will be reviewed as well as options and critical actions for a successful deployment of Ebola vaccines. The need for building a collaborative working relationships with all key partners was highlighted. Partners will finalize a framework and outline a plan for the deployment of Ebola vaccines, with a clear definition of roles, responsibilities and coordination mechanisms. These efforts are to support recommendations and country preparedness for the roll-out of the vaccine. Furthermore, the outcomes of the workshop will contribute towards addressing the needs that emerged from the WHO Executive Board special session on Ebola held on 26 January 2015. Particularly, in terms of ensuring the sustainability of the working groups on drugs and vaccines in order to support continued progress and commitment to the most affected countries in West Africa.

It is important to emphasize the need to maintain a clear communication with the experts involved in vaccine trials, those involved in community engagement and with the individuals and communities. Timely sharing of accurate information in a manner that can be understood will be key to the success of all efforts in relation to the introduction of Ebola vaccines.

Context and objectives of the workshop

Jean-Marie Okwo-Bele, Director, Immunization, Vaccines and Biologicals, Family, Women's, and Children's Health, WHO/HQ Geneva

The present status of the current epidemic was briefly outlined as the largest outbreak ever recorded; with almost 23 000 reported confirmed, probable, and suspected cases of EVD; and almost 9 000 reported deaths, in the three most affected countries: Guinea, Liberia and Sierra Leone. Six other countries (Mali, Nigeria, Senegal, Spain, the United Kingdom and the United States of America) have also reported a case or cases imported from a country with intense and widespread transmission. This first workshop of the Partners Group on Ebola Vaccines Deployment is to pursue planning and preparation goals for vaccines deployment, convening country representatives and partners to ensure coordinated efforts to affected countries for the use of a safe and effective vaccine. The most advanced Ebola vaccine candidates are now entering Phase 3 safety and efficacy clinical trials. Depending on the evolution of the epidemic, results from clinical trials and availability of vaccines, different vaccination strategies will be considered as part of the measures to control the outbreak.

Workshop objectives:

- To finalize the partners collaborative framework for the deployment of Ebola vaccines and to reach agreement on the next steps;
- To provide a synthesis on progress and evidence from Ebola vaccines development;
- To review options and strategies for deployment of Ebola vaccines, within the context of the epidemiological situation;
- To review critical actions for a successful vaccine deployment, focusing on community engagement and risk communication needs;

- To develop a draft outline of a collaborative plan for the vaccine deployment including outlines of operational plans with activities, deliverables and milestones for supply and procurement, deployment, monitoring and impact evaluation;
- To develop draft checklists to guide the country assessments, to support country readiness for the roll-out of the vaccine.

Part I: Presentations

Critical expectations from countries for the Ebola vaccine deployment: Sierra Leone

Dennis H. Marke, EPI Manager, Ministry of Health and Sanitation, Sierra Leone. The presentation is available upon request.

The index case of Ebola Virus Disease (EVD) was confirmed in Sierra Leone in May 2014. As of 21 February, 2015 Sierra Leone had 8 260 cumulative confirmed cases and 3 079 cumulative confirmed deaths. The outbreak affected all the 13 districts in the country, significantly overwhelming the health care system and disrupting daily life.

Four main expectations from Sierra Leone for the Ebola Vaccine Deployment Team were identified and presented:

- Successful vaccine trials;
- Rapid sharing and analysis of findings;
- Vaccine optimized to meet country needs;
- Financial and technical support for roll out.

Accelerated Ebola Vaccine Development

Vaseeharan Sathiyamoorthy, Technical Officer, Initiative for Vaccine Research, Immunization, Vaccines and Biologicals, WHO/HQ Geneva. The presentation is available upon request.

Once a Public Health Emergency was declared, WHO called for an international partnership to bring forward availability of high quality safety and immunogenicity data. This international partnership achieved unprecedented timelines for Phase 1 safety and immunogenicity generation for novel vaccine candidates. Two candidate vaccines started clinical evaluation in September-October 2014 (rVSV-ZEBOV [NewLink Pharmaceuticals / Merck / Public Health Agency of Canada] and ChAd3-ZEBOV [GSK/NIAID]) and one started clinical evaluation in January 2015 (Ad26.ZEBOV / MVA-BN-Filo, Johnson & Johnson / Janssen Pharmaceuticals / Bavarian Nordic). Multiple manufacturers will increase the chances of successful progress through development, testing and licensure for use, including opportunities for further improvements with the most advanced vaccines as well as with the pipeline vaccines (e.g. in presentation and stability of vaccines, and duration of protection).

Ebola epidemiology in West Africa and the implications for vaccine deployment strategies

Conall Watson, MRPharmS MFPH, Senior Registrar in Public Health Department of Infectious Disease Epidemiology, London School of Hygiene and Tropical Medicine, London. The presentation is available upon request

Incidence of Ebola virus disease has declined sharply in Liberia and Sierra Leone, but transmission is continuing in parts of Sierra Leone and notably in Guinea. Model projections suggest continued decline is likely in Liberia and Sierra Leone, but increased uncertainty over the future epidemic course in Guinea. This is consistent with field country situation reports, particularly in light of community resistance to the intervention of health workers. Ebola virus is largely transmitted along social networks, with adults at three times the risk of becoming infected than children. As transmission occurs during symptomatic illness or shortly after death, preventing cases through vaccination has the potential to enhance herd immunity and to interrupt transmission. Candidate vaccines as of yet, have not been tested for efficacy in humans and are to be tested in clinical trials in areas with ongoing transmission. There are substantial operational challenges facing the trials and any post-trial implementation. Should efficacy be demonstrated, vaccination of frontline workers is considered a high priority. In the communities, vaccine implementation strategies drawing on the surveillance-containment (including ring vaccination) approaches applied in smallpox eradication may be appropriate. Specific considerations include prevention of cases arising outside known contact networks, and planning around the specific properties of any effective vaccines, including any post-exposure prophylaxis potential, number of doses available and temperature-controlled storage and transportation.

Community engagement and risk communication: Vaccine trials in Guinea

Alain Epelboin, Medical Anthropologist and Film Maker, Centre National de la Recherche Scientifique (CNRS-MNHN), Musée de l'Homme, Paris

The necessity for an Ebola vaccine is undeniable, but due to a variety of different factors (e.g. the unpredictability of the disease in time and space, rumours, misconception, mistrust, mass psychogenic illness, violence and stigma), it might only be possible to administer the vaccine to front line health workers and to high-risk contacts. Within the Guinea context, a ring vaccination seems challenging and hardly feasible at present. In West and Central Africa the immunization programmes are weakened by structural problems (e.g. qualifications and experience of HCWs, lack of standard care material, cold chain equipment, etc.), political environment, administrative and economic constraints. It is therefore extremely challenging to envisage building on a fragile system, with a lack of synergy and listening capacity from the institutions. A community engagement strategy, based on a deep understanding of the local culture, and adaptable to the micro specificity of the local level is absolutely necessary to regain the trust of the community.

Community Engagement & Social Mobilization in support of Ebola Vaccine trial and wide-scale deployment in Liberia

Ukam Oyene, WHO/APOC Technical Adviser, WHO/Liberia. The presentation is available upon request.

In Liberia, UNICEF, WHO, USAID, Red Cross and other Partners have made significant investment to support government efforts in social mobilization pillar comprising: advocacy, media communication and community engagement. A strong leadership on the EVD response also plays an important role as well as buy-in from the legislative branch of the government, community leaders, public and private sector at all levels.

Community engagement and social mobilization activities are aimed at: 1) facilitating government ownership of the Ebola vaccine deployment program; 2) improving access to information about the Ebola Vaccine trial and wide-scale deployment; and 3) facilitating trust and acceptance of Ebola vaccine among community members, community and traditional leaders and other groups to engage their full participation. Periodic Intensification of Routine Immunization (PIRI), other vaccination programmes and Phase 3 vaccine trials could be potentially harmed, if community engagement is not scaled up to combat fear and rumours adequately. Alongside community engagement, efforts are highly needed in strengthening the coordination and training of health and social workers on interpersonal communication, documentation and monitoring of social mobilization interventions at county and sub-county levels. Four major strategic communication sub-systems have been identified:

- Advocacy: provide human resources and material support to sustain high level advocacy for trial and wide-scale introduction of Ebola Vaccine;
- Risk Communication and Community Engagement: build capacity for sustained risk communication and community engagement for trial and wide-scale introduction of Ebola vaccine;
- Media and Interpersonal Communication: strengthen capacity of media to support Ebola vaccination campaign;
- Planning, Coordination, Monitoring and Evaluation: strengthening capacity for planning, coordination, monitoring and evaluation.

Getting to zero transmission of EVD - Community engagement for successful EVD vaccine introduction in Sierra Leone

Saffea Gborie, Information Assistant, WHO/Sierra Leone. The presentation is available upon request.

In Sierra Leone, several partners are implementing social mobilisation activities at national and community levels under the leadership of the Ministry of Health and Sanitation's Social Mobilization Pillar. A recent Knowledge, Attitude and Practice (KAP3) study shows that comprehensive knowledge on Ebola continues to improve across the board due to ongoing EVD sensitization and community engagements. Misconceptions continue to decline, together with stigma and discrimination against survivors.

The community engagement strategy, to encourage community ownership includes building relationships between traditional and religious leaders and response teams; sensitization of key opinion leaders; and media engagement. Similar outreach activities are also underway as part of the vaccine study sensitisation and awareness activities. Three critical actions are identified for a successful vaccine deployment in Sierra Leone: coordination of partners; continued community engagement; and monitoring of vaccinated individuals for adverse effects of the vaccines.

Part II: Working Group sessions and plenary discussion

The Steering Group (SG) and the three Working Groups (WG) (Country Implementation; Monitoring, Surveillance and Impact Evaluation; and Vaccine, Supply and Procurement) reviewed and discussed in individual groups their respective terms of reference (ToRs), key activities, deliverables, milestones, group composition and group communication. Each group presented their final products, followed by a plenary discussion.

The GEVIT Partners planning framework is presented in Annex 4.

Discussion points

The following activities are within the scope of the Ebola Vaccine Deployment Team:

- Vaccines procurement;
- Implementation and roll-out;
- Surveillance, monitoring and evaluation of impact;

Recovery of health systems and immunization programmes, although crucial, is not within the scope of work for the Ebola Vaccine Deployment Team.

One of the recurring topics remained the funding requirements for deployment of the vaccine.

Potential vaccination scenarios were identified by WHO and partners in October 2014, among which the following three target groups are the most likely to be prioritized in the current context: **a) health care workers (HCW); b) community Ebola respondents (CER); and c) contacts providing home care of cases and ring vaccination of subjects.** The initial deployment plan will be generic and once accurate data emerge from country assessments, the plan will be further developed. The plans will only be finalized after SAGE guidance on targeting recommendations.

For country involvement, after group discussion it was decided:

- The SG will communicate with MoH to rapidly identify appropriate points of contact;
- The WG leads will establish contact with identified country individuals;
- The WG will provide a questionnaire on information needed to plan for deployment;
- The SG will provide a consultant/team of consultants to assist in country planning activities in coordination with WG leads.

The SG acknowledged during this first workshop that work is being accomplished in a dynamic and fast changing environment. Therefore, the SG will need to ensure the following at all times:

- Clearly defined mandates of the different partners;
- Partners' willingness and flexibility to work adapting according to changes in information and assumptions;
- Partners' preparedness to expedite internal review processes;
- Global commitment to work together in good trust

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