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Beating the odds: Successful establishment of a Phase II/III clinical research trial in resource-poor Liberia during the largest-ever Ebola outbreak

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ABSTRACT

It has been argued that a country such as Liberia, not fully recovered from the devastation of decades of civil unrest, lacked the appropriate ethical and regulatory framework, basic human and health care services, and infrastructure to carry out clinical trials according to international standards of quality during a public health emergency. However, as Liberia, Sierra Leone, and Guinea were being ravaged by the largest and most devastating Ebola Virus Disease (EVD) outbreak ever recorded, the topic of conducting clinical trials of experimental vaccine and treatment candidates in these resource-poor countries generated the keen interest and concern of scientists, researchers, physicians, bioethicists, philanthropists, and even politicians. Decisive action on behalf of the Liberian government, and a timely positive and supportive response from the United States (U.S.) government, led to the formation of PREVAIL (Partnership for Research on Ebola Vaccines in Liberia) – a clinical research partnership between the two governments. Within a span of 12 weeks, this partnership accomplished the unimaginable: the successful initiation of a Phase II/III vaccine clinical trial for EVD in Liberia. This paper will discuss the dynamics of the research collaboration, barriers encountered, breakthroughs realized, key elements of success, and lessons learned in the process.

1. Background/aims

Prior to the recent West African EVD epidemic, Liberia's emergence from decades of civil unrest, which included two successive civil wars, resulted in a ranking among the world's least developed countries. Its fragile healthcare system lacked adequate infrastructure, human capacity, and access to safe therapies, medical equipment and limited provision of healthcare services [1,2]. By August 2014, Liberia had become the most affected country in the outbreak, reporting more than 200 cases a week for 3 consecutive weeks. At that time, the fatality rate was reported as 53%. President Ellen Johnson Sirleaf declared a state of emergency in Liberia on August 6 [3], followed a few days later by a declaration by the World Health Organization (WHO) that the outbreak was a public health emergency of international concern [4]. Healthcare workers were dying, and many who were not infected with Ebola abandoned their posts. The country had insufficient Ebola treatment units, isolation centers, and laboratories to accommodate the rapidly escalating infection rate and death toll of this new devastating disease; and unsafe burial practices persisted. Many hospitals were forced to shut down, while EVD patients and high-risk communities were isolated and treated with disdain by the Liberian police. As protestors demonstrated throughout the country in opposition to the actions – and apparent inactions – of their elected leaders, confidence in the Liberian government reached an all-time low [5,6]. In this desperate circumstance, Liberia's Minister for Health and Social Welfare, Walter Gwenigale, wrote to Sylvia Burwell, U.S.

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Secretary of Health and Human Services, requesting that the two entities collaborate to conduct research on promising therapeutics and vaccines for EVD [7].

2. Systematic approach

2.1. Research partnership formed with bilateral support from the highest levels of government

Minister Gwenigale's request to form a "partnership" set forth an organizational structure and process that was both inclusive and flexible, leveraging a broad range of expertise from both countries while permitting resolution of conflicts and logistical issues with urgency. He and Secretary Burwell each appointed leaders to develop the partnership. In addition, the Liberian Minister of Health and the U.S. Ambassador to Liberia were available to resolve conflicts and barriers that required high-level intervention.

Experienced and trusted individuals from each country were selected to share the leadership of key functional areas (see Fig. 1) critical to establishing a clinical research program in Liberia that could initiate and conduct clinical trials according to international standards of ethics and quality. An organizational governance chart was established at the onset to mitigate any conflicts and to articulate an authority matrix. In Liberia, the Ebola response effort was led by an Incident Management System (IMS) consisting of a national task force and technical expert committee.

The IMS was developed by the Liberian Ministry of Health (MOH) to oversee the management of the Ebola-related activities [8]. This group included Liberians with training and experience in epidemiology, several aspects of clinical research, and highly infectious diseases. The Liberian MOH appointed two individuals - a physician and medical researcher who is the IMS Coordinator for EVD research, and a biomedical researcher who heads the Liberian Institute for Biomedical Research - to represent Liberia in the scientific leadership of the partnership. Similarly, the Deputy Director for Clinical Research and Special Projects from the U.S. National Institute of Allergy and Infectious Diseases (NIAID) was selected to lead the U.S. side of the partnership.

In addition to the medical/scientific leadership, operational officers from both the U.S. and Liberia were appointed to provide oversight and assure integration among the functional teams. The individuals selected from each of the countries came with decades of cumulative experience in clinical research and operational project management. In addition, the U.S. Embassy in Liberia and relevant government institutions in Liberia (i.e., Ministries of Health, Justice, Foreign Affairs, and State) promptly and consistently provided invaluable in-country expertise, and logistic and financial support to the partnership as needed.

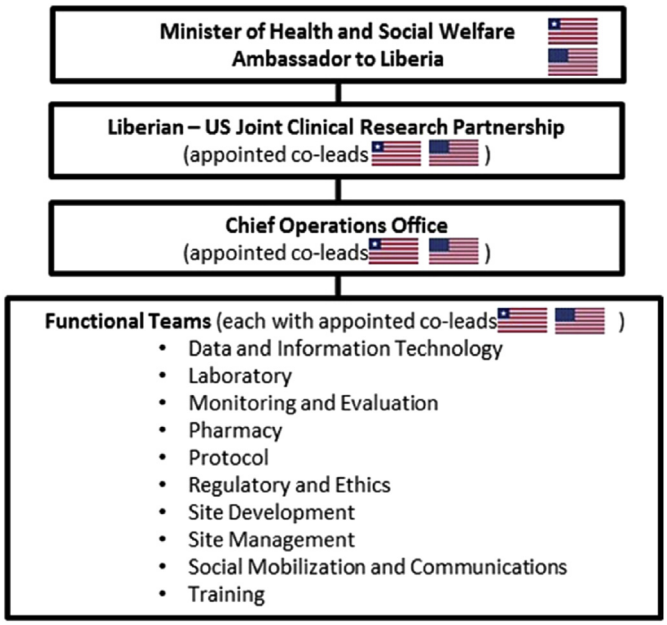

Fig. 1. Organizational structure of the Liberian-US research partnership.

With the daunting task of establishing an effective framework in which to accomplish the objectives of the partnership in a condensed time frame of days to a few weeks, ten functional teams were established with the responsibilities of developing strategies based on identification of their respective tasks, project timelines, and relative dependencies. Each team was led by and consisted of representatives from both countries who worked together to quickly resolve or escalate barriers as they were identified.

It was quickly realized that working on this partnership necessitated face-to-face collaboration at most, if not all times. To build the partnership, establish trust, and work collaboratively to launch the partnership's first clinical trial, 36 Americans made a total of 68 trips and spent 1032 days in Liberia between October 2, 2014 (when Secretary Burwell accepted Minister Gwenigale's request) and February 2, 2015 (when the first participant enrolled in the partnership's first clinical trial).

2.2. Social Mobilization and Communication established as a key functional area

Social mobilization is recognized as a process of engaging a range of stakeholders to raise awareness within a specific population, obtain their buy-in, and participate in a particular objective [9]. One of the initial actions of the partnership was to identify Social Mobilization and Communication (SMC) as a key functional area needed to establish the clinical research program.

Although none of the clinical research networks previously developed by the U.S. co-leads had leveraged SMC concepts, it was clear that implementation of SMC principles and strategies had proven effective during the ongoing Ebola outbreak and would be critical to the success of the partnership's clinical research effort.

In the wake of the outbreak, community leaders took ownership of the response efforts by establishing community-based Ebola task forces; these groups of predominantly young people voluntarily took on the responsibility of providing awareness and sensitization on the preventive measures of the EVD. They ensured that a robust contact tracing and case reporting mechanism was put in place and that homes that were quarantined received adequate community support in terms of food, water, and other basic essentials. Realizing the effectiveness of the community-based SMC strategies, the Liberian government through the MOH, decided to leverage these strategies thereby strengthening the capacity of the task force and other community volunteers who later became ambassadors of change. Messages were communicated via the print and electronic media through press releases, talk shows, radio jingles and dramas. These strategies resulted in adequate information dissemination, community collaboration, and a more effective response to the outbreak [10,11].

With the onslaught of information about EVD and the current outbreak, it was important to communicate information that would promote dialogue with the community members about their concerns, dispel rumors, and generate trust between the public and the research partnership [12,13]. The PREVAIL SMC team (consisting of communicators, mobilizers, scientists, and coordinators) first engaged key national and local stakeholders to garner their support in making community members aware of the objectives and

collaborate in the planning and conduct of the proposed clinical research program. These stakeholders included national politicians, legislators, and trusted elected or appointed leaders (i.e., county superintendents, city mayors, governors, commissioners, traditional, religious, and community leaders).

The SMC team held frequent community engagements and extensive question and answer sessions with stakeholders at all levels, including community dwellers and the media, in an effort to enhance understanding, dispel myths, address concerns, and allay fears about EVD and clinical research.

The high incidence of EVD infections and deaths in the region and the government's delay in providing timely information on the disease created myths that posed major challenges for the research. During the social mobilization and community engagement to inform the communities about the research, the SMC team learned that community dwellers believed the Ebola virus is man-made, and the experimental vaccines would be given to infect more people with the virus to generate more funding to the government. They also expressed concern that those who took the vaccine would die during the rainy season because the highest peak of the spread of the Ebola virus in Liberia occurred during the previous rainy season. They even shared their beliefs that the Ebola virus outbreak in Liberia was an instrument of the Liberian government to collect plasma for commercial purposes, and they believed that the vaccine trial was being conducted for the same purpose. The community dwellers also had misgivings about the word "trial", which they believed should be used for animals, and were more comfortable with the use of the word "study" for humans [14,15]. All of these concerns were factored into the information, education and communication and behavior change communication messages that were prepared in simple English and local vernacular to deliver to all levels of the community through dialogue, written materials, songs, and dramas enacted by mobile theater.

Because of these consultations with the community leaders and members, changes were made to the study procedures, such as expansion of the informed consent process to include a general information session with pictorial guides and a private session to address more personal concerns or questions. There was still a degree of stigma and discrimination associated with participation in the vaccine trial, as some members of the community believed that participants were being vaccinated with the Ebola virus and would eventually infect others in the community. The assignment of participant trackers ensured consistent contact with the participants throughout the study and served as liaisons between the participants and the research team while maintaining the confidentiality of the participants' involvement in the study.

As the vaccine trial progressed, and new clinical trials were initiated, the SMC team was constantly engaging the population to inform them of new information, as well as to seek critical feedback from them. This occurred through advocacy meetings with traditional, religious, political, and community leaders; targeted community meetings with dwellers of affected communities; press releases and media briefings; appearances on radio and television programs; and communication through songs, dramas, and mobile theater.

The strategies used by the SMC team to engage the population at all levels and communicate at the most basic levels resulted in an establishment of trust in the PREVAIL organization. The SMC team was then perceived as a link between the communities and the research scientists. With the increased understanding of the objectives and outcomes of the research, there was also a shift towards increased trust in the government as an engaged member of the partnership.

2.3. Regulatory approvals

The decision to conduct a Phase II/III clinical trial to investigate the safety and efficacy of two promising vaccine candidates was based on recommendations from a World Health Organization (WHO) panel of experts to accelerate testing of vaccines and treatments that had shown promise in animal studies [16].

The partnership had to ensure that the study would be scientifically, ethically, and clinically appropriate and that it would adhere to globally accepted standards for protecting the rights and safety of human clinical research participants. The clinical trial protocol was submitted to the Liberia Medicines and Health Products Regulatory Authority (LMHRA) and the U.S. Food and Drug Administration (FDA), the Institutional Review Board (IRB) of the National Cancer Institute (NCI) at the U.S. National Institutes of Health (NIH), and the Liberian National Research Ethics Board (NREB) for required regulatory and ethics approvals. Under optimized settings, obtaining such approvals from multiple agencies is an arduous, time-consuming process that involves a series of review and edit cycles – an effort that typically takes several months. Despite the public health emergency, these processes were still required before a clinical trial of experimental vaccines could be initiated in Liberia. However, several months was a luxury that no one could afford in light of the rapidly escalating EVD epidemic. In several months, the outbreak could potentially be over, with thousands more infected or dead before the trial could even begin.

In addition to the requirements for regulatory approval, there was an additional requirement in Liberia for political approval from the President of Liberia. This approval was being challenged by a group of Liberian politicians, lawyers, human rights activists, ethicists, journalists, and academicians who were opposed to the concept of conducting clinical research with inadequate healthcare facilities, in a research-naïve population, and during an ongoing public health crisis. There were concerns that potential study participants with a low literacy rate would not get a full understanding of the scientific objectives of the research and would not be able to adequately provide informed consent. The fact that the vaccines had not been sufficiently tested in humans supported the argument that Liberians are humans – not animals – and therefore should not be used in the research. Some also questioned the ethics of administering unapproved or unlicensed vaccines and giving false hope to people who were at risk of exposure to a deadly disease, and there was the sentiment that participants should not receive financial compensation to take the trial vaccine. Another strong objection addressed the contribution of Liberians to the eventually lucrative commercialization of one or more vaccines without the accrual of any financial benefit to the participants or the host country.

The PREVAIL researchers were quite aware that concerns about the ethics of conducting clinical trials in West Africa were not without merit, largely because of past experiences that had major implications on the conduct of pharmaceutical clinical research in West Africa (e.g., the Pfizer Trovan trial in which 11 Nigerian children died during an epidemic of meningococcal meningitis [17]). However, the concerns raised by Liberians pointed more to the infamous Tuskegee Experiment of untreated syphilis in Black men [18]. The PREVAIL leadership and members of the SMC team fully recognized the importance of adequately addressing this specific sensitive concern. This led to the careful crafting of simple and comprehensible messages around the principles and ethics of clinical research that were used in stakeholder and community consultations. The messages, once approved by ethics boards in both countries, were also used in information sessions for the clinical study volunteers. Extensive attention was paid to addressing the numerous questions and concerns about the informed

consent process, the risks of being injected with an unlicensed vaccine that had limited testing in humans, and the danger of possibly being infected with Ebola because the vaccine was reported to contain a "harmless piece of the Ebola virus" as worded in the study informed consent document. Failure to provide clear and accurate responses to these questions had the potential to destroy any trust in PREVAIL and derail the research and response effort.

A series of meetings was spearheaded by the Office of the Vice President of Liberia to ensure that all concerns expressed were sufficiently addressed before a recommendation for political approval to conduct the vaccine clinical trial could be made to the President. The outcomes of these meetings prompted further discussions with key stakeholders representing the Liberian and U.S. governments. One important result of such discussions was the provision that post-trial access to the vaccines and treatments, if proven effective and licensed, would be made available to all research participants involved in these clinical research trials.

In parallel, international requirements pertaining to credentialing and import/export procedures, as well as logistical details such as laboratory testing and pharmacy facilities, identification of equipment, shipping, storage, and meeting spaces had to be addressed, and were resolved quickly with the availability of the high-level support of both the Liberian and U.S. governments through their respective representatives in the partnership. In less than 30 days, all requirements were satisfied, and approvals were received for the planned Ebola vaccine clinical trial to proceed.

2.4. Ethics considerations

2.4.1. Clinical trial design

There were conflicting ethical views on what types of clinical research trials would be appropriate to implement in an ongoing Ebola outbreak. Of the clinical trial designs that were discussed, two options were given the greatest consideration: ring or cluster vaccination and randomized placebo control. In the ring vaccination design, individuals who are at increased risk of infection and developing the disease within a few weeks are recruited based on their social or geographical connection to an active case, and designated as a 'cluster'. This ring design would allow for open-label administration of investigational product to all residents of a specific cluster, and the participants would be randomized to either immediate or delayed vaccination [19,20]. On the other hand, the randomized placebo-controlled trial design would assign participant exposure to a potentially effective product by chance, with the possibility that a percentage of the study participants – the placebo group - would not receive any investigational vaccine. After much consideration and deliberation, the partnership considered that a randomized placebo-controlled clinical trial design would have the greatest likelihood of providing more definitive results, and could potentially lead to rapid licensure and availability of effective vaccines [21].

The PREVAIL vaccine clinical trial was initially designed to enroll 28000 healthy adults living in Liberia, with priority being given to healthcare workers; laboratory personnel; and ambulance, burial and surveillance team members. Children, pregnant women and lactating mothers were excluded from enrolling because of insufficient safety data on these categories of people. A sub-group of 600 participants would undergo additional assessment to provide more information on the safety and immunogenic response of the experimental vaccines.

With the greatly welcomed waning of the EVD infection rate in Liberia by March 2015, the regulatory agencies and ethics review boards of both countries agreed that the study should not continue with the plan of enrolling 28000 participants. A final enrollment target of 1500 was supported by the independent Data Safety Monitoring Board (DSMB), which consisted of physicians, scientists and statisticians from both Liberia and the U.S. This group continuously monitored the trial data to ensure the safety of the trial participants.

2.5. Capacity building and knowledge transfer

Minister Gwenigale's request for assistance also identified the need to strengthen the Liberian healthcare system. In every functional area and aspect of this partnership, the methods chosen to conduct EVD clinical research were those that also would contribute to building and sustaining healthcare capacity in Liberia. Liberians with expertise in healthcare and clinical research were recruited into the partnership. This helped to establish trust with potential participants, as well as to employ those who had lost their jobs due to the closure of medical facilities and programs during the Ebola outbreak. Over 340 Liberians were hired, including doctors, nurses, physician assistants, pharmacists, laboratory technicians, and psychosocial counselors. The partnership also was responsible for employing medical janitorial staff, security guards, and various administrative, logistics, and operations staff.

Clinical research capacity building involving knowledge transfer to the Liberians responsible for the day-to-day operations was essential prior to the beginning of the trial. The goal of PREVAIL is to prepare Liberians to independently operate the full scope of the clinical trial. Achieving this goal would result in long-term sustainable benefits for the partners, Liberia, and strategic global health initiatives. According to the National Bioethics Advisory Commission, "A unique feature of international collaborative research is the degree to which economically more prosperous countries can enhance and encourage further collaboration by leaving the host community or country better off as a result [22]."

Didactic education and hands-on training for clinical staff were provided by competent professionals from the Liberian Ministry of Health, the U.S. Centers for Disease Control and Prevention (CDC), and the NIH, who provided training on the use of Personal Protective Equipment (PPE), Good Clinical Practices, Informed Consent, and policies and procedures related to working in the vaccine clinic. Knowledge deficits were promptly addressed with additional training sessions or refresher training.

Capacity-building commitments are also reflected in the decisions to improve the existing infrastructure. While the vaccine trial might have been easily conducted from the U.S. Embassy, or in makeshift army tents, the team opted for a more sustainable site that could be used for future trials. The partnership identified and negotiated the use of a section of Redemption Hospital, a government-run hospital located in one of the most severely Ebola-affected areas of Monrovia, in which to conduct the trial. During the height of the outbreak, Redemption Hospital was used as a holding center for Ebola patients, and lost a good number of its staff to EVD. The Redemption facilities had been neglected over time and had no laboratory to conduct certain tests needed for the trial. Within 17 days, the building was renovated to a functional clinical trial site – complete with a fully operational state-of-the-art medical lab. This site was easily accessible to many of the targeted study participants who resided in and around the vicinity of the hospital.

3. Overall outcomes

It took a record 12 weeks to bring a Phase II/III, randomized, controlled, EVD vaccine clinical trial from concept to enrollment in Liberia – a low-income country in the midst of a national state of emergency due to EVD, and fraught with infrastructure, financial, political, and healthcare challenges. This was accomplished through the concerted and rapid efforts of a partnership between

two nations who were committed to achieving this goal despite overwhelming odds. Key elements of PREVAIL's success included the establishment of a strong organization in which all members were treated and respected equally, careful selection and execution of plans that would build and sustain relevant capacity in the host country, and active involvement and buy-in at the community level.

The partnership demonstrated the impact of bi-directional knowledge transfer. While much of the technical knowledge transfer was from U.S. to Liberian staff, the Liberians were not always on the receiving end of the learning experience. Liberian staff educated their American counterparts on essential aspects of operating within the Liberian setting and cultural context. American colleagues learned how to improvise when certain resources such as water or electricity were temporarily lacking or absent; they learned that religion and family were essential components of one's professional life; and they learned that, in Liberia, family was not necessarily defined by a commonality in bloodline and heritage, but by a commonality in spirit and purpose.

The PREVAIL vaccine trial exceeded its initial recruitment target of enrolling 600 participants in 4 months. Within 3 months of vaccinating the first trial participant, 1500 volunteers had enrolled in the first vaccine clinical trial for EVD to be conducted in Liberia. The clinical research site established at Redemption Hospital now boasts one of the best medical laboratories in Liberia, with state-of-the-art equipment that will remain in the country for use by its citizens long after the clinical trial has ended. Liberian laboratory technologists have been trained and are now self-sufficient in operating the equipment.

Evidence of the capacity of the Redemption site and performance of the vaccine trial clinical site staff has been objectively observed by the DSMB. They have commended the trial team for the rapid enrollment, outstanding data quality, and exceptional participant retention and follow-up rate of over 98%.

PREVAIL has also launched an EVD treatment trial entitled, *A Multicenter Randomized Safety and Efficacy Study of Putative Investigational Therapeutics in the Treatment of Patients with Known Ebola Infection*, which has enrolled 72 participants at 11 sites in the U.S., Guinea, Sierra Leone, and Liberia.

Additionally, PREVAIL launched a third clinical trial to evaluate the natural history and clinical sequelae of EVD in Ebola survivors and their close contacts over a 5-year follow-up period. Between 17 June and 3 December 2015, this trial had enrolled 1005 of Liberia's documented 1546 Ebola survivors, and 530 of their close contacts, at 3 newly renovated clinical sites that can be used for future clinical research projects.

4. Conclusions

The value and tenacity of the human spirit is often underestimated, especially in the scientific arena in which data and facts dominate. PREVAIL illustrates the power of the human spirit: the persistent and unfailing desire to succeed. This partnership was able to accomplish the difficult task of establishing a distinctive EVD clinical research program in Liberia amidst significant logistical adversity and impractical timelines. While much was accomplished because of the financial and human resources that were made available for the program, success could not have been achieved without the effective strategies that represented a unique mix of American and Liberian ideas and expertise; the common passion, vision, integrity, trust, and committed relationships of the team members that formed the partnership; and the courage and tenacity required to prevail in the most difficult circumstances. Clinical research on emerging and re-emerging infectious diseases in the developing world presents enormous challenges; and the experience of the Liberia-U.S. Joint Clinical Research Partnership presents a classic example. Minister Gwenigale wrote in his request to Secretary Burwell, "The fruits of research must be relevant in the societies and population where the problems on which research is conducted are the gravest." It is hoped that the fruits of the research conducted by PREVAIL will extend beyond the clinical trial results that may inform and strengthen healthcare in Liberia, West Africa, and throughout the world. The accomplishments of the Liberia-U.S. Joint Clinical Research Partnership have demonstrated that the unimaginable can be achieved in the midst of dedication, persistence, and hard work. More in-depth reviews of the challenges and success factors in each of the functional areas of this partnership are necessary to build upon this experience and to be better equipped to mount a clinical research response in the event of a future infectious disease outbreak. The authors foresee that the path chosen to launch the PREVAIL clinical research program can serve as an effective model to build capacity and conduct quality clinical research in resource-poor settings.

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