

Collaboration of the NIH and PHS Commissioned Corps in the International Ebola Clinical Research Response

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The U.S. response to the Ebola epidemic resulted in many federal agencies assessing their ability to respond to global threats and improve the efficiency of humanitarian efforts.

The Ebola epidemic of 2014-2016 challenged many federal agencies to find creative ways to help address the vexing problems created by the spread of the disease. There were many factors complicating the response, including the recovery from civil wars in Liberia and Sierra Leone that decimated the physical infrastructure as well as education and other vital services.

The response from the U.S. and the global community took many forms: Not only was there a need for the typical medical care support, but also for basic public health systems to track the spread of disease, provide clean water, and dispose of infectious waste. Because no known preventive vaccines or therapeutics existed for those infected, the recognition of a research component to the response became

abundantly clear as the epidemic continued. As a result, the National Institutes of Health (NIH) and the USPHS Commissioned Corps (Corps) serendipitously found themselves allied in a mutually beneficial relationship in the establishment of an Ebola clinical research program in West Africa.

This article describes the events that led to the NIH and Corps participation in the Ebola response, the roles filled by the Corps in supporting the NIH, and the lessons observed from that collaboration. Also presented are considerations regarding preparation of a clinical research response to future outbreaks.

NIH CLINICAL RESEARCH FIRST RESPONSE

The 2014-2016 Ebola epidemic in West Africa demonstrated the need

for federal agencies to reassess their capacity to respond to global threats to protect the health security of the U.S.¹ The outbreak also challenged the U.S. government to mobilize unique resources that matched the need of this international (and domestic) response.

In 2014, President Barack Obama announced that the U.S. would launch a government response to the Ebola effort. Although a comprehensive research and development program already was in place to establish Ebola virus disease (EVD) countermeasures, no FDA-approved diagnostics, therapeutics, or preventive vaccines were readily available. Fortunately, FDA regulations regarding emergency use authorizations allowed for the use of several EVD diagnostics during this outbreak.² However, the development of drugs and vaccines specific to Ebola had yet to make their way to phase 1 safety studies.

Two vaccine products went into phase 1 studies in the U.S. within months of the declaration of the emergency.^{3,4} Additionally, the NIH had organized a collaborative effort between the U.S. government and

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Figure 1. Preparing Treatment



A Commissioned Corps pharmacist prepares ZMapp at an Ebola treatment unit in Sierra Leone.

academic community to identify a research strategy for the evaluation of therapeutics.⁵ Regardless of the state of countermeasures and research proposals, the initial need was for disease control measures and care for Ebola patients. The CDC took the lead in working within the international community to establish an incident management system that could help the impacted countries enact mechanisms to bring the epidemic under control.⁶

As the epidemic progressed, leaders in the Corps and the NIH responded on pathways that eventually would intersect. One of the unfortunate outcomes of the early efforts of improperly protected health care providers was the unintentional transmission of Ebola.⁷ The Corps identified the need to provide high-level care to the health care worker community as one incentive to motivate health care workers to volunteer for hazardous duty inside Ebola treatment units (ETUs).^{8,9} Engulfed in the epidemic response, the U.S. government through the National Security Council and secretary of the Department of Health and Human Services (DHHS) evoked its statutory authority to deploy the Corps (42 U.S. Code 204a).

In the first week of October 2014, the Corps sent an advanced echelon team to assess the situation, partner with key host country and international stakeholders, and begin establishment of the U.S. government's first ever ETU. With logistics, security, and resource support from the DoD and response coordination from the U.S. Agency for International Development, the Corps then deployed the first of four 70-person team rotations to staff the Monrovia Medical Unit (MMU), an ETU specifically dedicated to the treatment of Ebola-infected health care workers. At the

time, it was the only ETU specifically dedicated to health care workers in all of Africa. The MMU operated until May 2015 and provided direct patient care for health care workers with Ebola, malaria, and other illnesses.^{8,10}

In August 2014, representatives from the CDC met with Liberia's Minister of Health and Social Welfare Walter T. Gwenigale, MD, to discuss the range of available options that could facilitate a better understanding of the prevention and treatment of the disease. This meeting resulted in a letter dated August 22, 2014, from Dr. Gwenigale to then DHHS Sylvia Burwell, requesting a research response. Secretary Burwell responded on October 2, 2014, describing the immediate dispatch of the deputy director for clinical research of the National Institute of Allergy and Infectious Diseases (NIAID) to Liberia to engage in initial discussions with the Liberian

minister and other key Liberians involved in the response.

Representatives from the CDC and the commander of the Corps' Ebola response (and acting deputy surgeon general) were included in those initial meetings, which led to a recognized need for a robust clinical research program of the highest ethical and scientific standards consistent with the expressed requirements of Liberia.¹¹ A second and third trip to Liberia with larger U.S. teams resulted in an agreement signed on November 19, 2014 for the scientific investigation of strategies that tested interventions for treatment, control, and prevention of Ebola.¹²

The agreement led to the establishment of the Partnership for Research on Ebola Virus in Liberia (PREVAIL) to identify research priorities in a collaborative manner between Liberian and American scientists. The first protocol, a vaccine study, was launched in early

February 2015.¹² This monumental task involved the support of hundreds of Liberians and dozens of NIH staff who volunteered for rotations to Liberia. Of the 108 volunteers from within the NIH, 18 were PHS officers. Shortly after launching the vaccine study, the next priority was initiating the treatment study. This study was delayed primarily due to ZMapp (Mapp Biopharmaceutical, San Diego, CA) production limitations. ZMapp, a monoclonal antibody cocktail, was the first Ebola therapeutic product to be evaluated in a randomized trial.^{5,13}

During the planning for the study, NIAID staff in Liberia met with Corps staff of the MMU to discuss the logistics associated with implementation of the ZMapp protocol at the MMU. During that meeting, the NIAID deputy director for clinical research expressed interest in obtaining Corps support from outside the NIH to sustain the research effort in West Africa. More specifically, additional pharmacy and laboratory staff were needed to augment NIH research operations. At the time, the MMU commander had recently transitioned from service as the acting surgeon general and was in a unique position to recommend additional Corps resources that could help in the research response.

The February 2015 discussion resulted in the establishment of an NIH/PHS research partnership that continues to exist. This new opportunity was not a significant stretch for the PHS as there was great interest from the Corps for responding to the Ebola crisis. The enthusiasm was consistent with the overall ethos of the Corps, which as a service was composed of highly qualified active-duty, deployable, uniformed, public health professionals who respond to public health crises at home and

abroad. To date, 19 Corps officers from outside the NIH have deployed in support of the NIH Ebola clinical research program. An additional 18 Corps officers assigned within the NIH also volunteered for duty in West Africa. Of the 37 Corps officers supporting the NIH clinical research program, 7 served on more than 1 rotation.

PROGRAM EXPANSION

The Ebola clinical research program expanded over time from the initial PREVAIL vaccine study to include studies of therapeutic agents, natural history in Ebola survivors, and an additional vaccine study. The PHS officers have been integral in conducting these studies. The initial study implemented in Liberia, known as PREVAIL I, involved the evaluation of 2 vaccine strategies vs placebo.^{12,14} In addition to the NIH-based Corps officers supporting the study, the Readiness and Deployment Operations Group (RedDOG) initiated deployments for an additional 2 pharmacy and 7 laboratory officers to support this study. During the deployment, the pharmacists were asked to extend their reach to Sierra Leone and later to Guinea to help establish PREVAIL II, an evaluation of ZMapp in the treatment of Ebola.¹³ A total of 9 Corps pharmacists, 2 nurses, and 3 physicians deployed to Sierra Leone or Guinea to assist in the PREVAIL II study.

As the epidemic came to an end in Liberia in May 2015, the need for a long-term assessment of Ebola survivors was recognized, resulting in PREVAIL III.¹⁵ Noteworthy in the survivor study was an ophthalmic substudy led by a Corps officer assigned to the National Eye Institute.^{16,17} The survivor study also identified that the persistence of the Ebola virus was longer than previ-

ously known and that sexual transmission via semen from infected males remained a potential mode of transmission.¹⁸ To address the lingering viral load, a study of an antiviral drug was initiated in Liberia in the summer of 2016, PREVAIL IV.¹⁹

Four Corps pharmacists helped train Liberian pharmacists to establish and sustain this randomized, double-blind, placebo-controlled study. Most recently, Corps pharmacists were deployed to support the initiation of the Partnership for Research on Ebola Vaccines (PREVAC), a collaborative partnership with researchers from Liberia, Guinea, and Sierra Leone with cosponsors from the NIH, Institut national de la santé et de la recherche médicale (Inserm) in France, and the London School of Hygiene and Tropical Medicine in the United Kingdom.²⁰

Deployment Procedures

As previously mentioned, 108 staff (civil service, assigned PHS, and contractors) from within the NIH volunteered for deployment to assist in the clinical research Ebola response. The typical rotation for those volunteers was limited to 3 weeks to minimize the disruption of their normal work assignments. Volunteers were organized into small teams within the Division of Clinical Research were composed of the right mix of physicians, nurses, medical technologists, and pharmacists. The team ensured that staff obtained official government passports, scheduled airline reservations, and received an orientation to the deployment setting as well as to the research studies (Table). Additionally, the team coordinated the voucher submission process for reimbursement of expenses on return from the country. An additional team member was stationed in Liberia to coordinate the housing and

transportation arrangements with a local hotel near the U.S. Embassy.

Within a week of the February 2015 initial meeting in Liberia to establish the NIH/PHS collaboration, the NIH deployment team met by phone with the Corps' RedDOG to discuss initial requirements (eg, number of officers needed, disciplines, time lines, and documentation needed for deployment). These initial discussions resulted in the establishment of more formal processes that evolved over time as the 2 organizations gained experience. Based on the identification of the numbers and types of officers needed, RedDOG used procedures similar to the process for staffing the MMU. A communication went out to the Corps seeking interested officers.

Deployment slots were filled based on the personal availability of the officer and coordination with their immediate supervisor and agency. Officers needed to meet medical clearance requirements and provide current health care provider licensure information. Additional training requirements needed to be completed (eg, U.S. State Department training and good clinical practice [GCP] if not already current). Corps officers also took part in the NIH orientation program for deploying personnel to familiarize them to the situation on the ground in West Africa and the specific clinical research protocols that they would encounter. Given that most of the Corps officers were coming from outside the NIH, the onboarding activities required significant attention to detail as procedures for arranging travel (eg, passport, visa, and airline reservations) and processes for reimbursement of travel/per diem pay differed from more traditional deployments directed through the Corps headquarters.

Figure 2. Data Collection



A study coordinator in Sierra Leone collects data on case report forms via phone from across the hot zone.

Commissioned Corps Roles in the Research Response

Whereas the establishment of the research program in Liberia was based primarily on relationships forged over a 2-month period by the NIAID deputy director for clinical research and staff, the extension of the research program into Sierra Leone (March 2015) and Guinea (June 2015) was on a substantially shorter time line. As a result, Corps officers were thrust into roles that immediately employed their leadership and diplomacy skills.

In Sierra Leone and Guinea, the NIAID deputy director for clinical research established initial relationships within the countries. However, Corps officers found themselves in regular interactions with regulators in the Ministry of Health to ensure that applications were complete and import permits for incoming shipments were cleared. Additionally, the research collaboration in Sierra

Leone was coordinated through an investigator assigned to a military hospital converted into an ETU. The Corps officers were well suited to maintain and build on that relationship in expanding the protocol to other ETUs throughout Sierra Leone. A site established by the CDC within the Sierra Leone Ministry of Health coordinated ZMapp storage. The Corps officers formed working relationships with the CDC team to establish and improve cold-chain logistics and transportation of the ZMapp to the various ETUs around the country. Corps officers were integral in working with the in-country contract hiring agency. Activities included establishing criteria for clinical research positions, providing input on the interview of respective candidates, and training staff as the team formed. In Sierra Leone, local staff members were hired to work at specific facilities as research

Table. Agencies Responsible for Onboarding Activities

Onboarding Activity	PHS RedDOG	National Institutes of Health Deployment Team	U.S. State Department
Official passport/visa	✓		
Physical clearance/immunizations/deployment medicines	✓		
Readiness bag	✓		
Country orientation		✓	
Research protocol organization		✓	
Airline reservations		✓	
Good clinical practice training		✓	
State Department training			✓
Advance pay		✓	
Airport reception in-country			✓
Transportation from in-country airport to hotel			✓
Lodging		✓	
Transportation within country		✓	
Interpreters in Guinea		✓	
Travel pay		✓	

coordinators working with the health care delivery teams.

The U.S. team consisted of a physician, nurse research coordinator, and a pharmacist travelling to the sites with a logistics/operations staff member remaining in Freetown.

Fortunately, a Corps nurse on the team had been part of the initial MMU deployment and was trained to work in a special care unit at the NIH for patients with highly contagious infections. This practical experience was essential in the establishment of procedures in a hazardous environ-

ment for the administration of the IV ZMapp, monitoring of adverse effects (AEs), provision of medications to mitigate infusion-related reactions, and documentation of those AEs.

The U.S. research team regularly departed Freetown early in the morning 7 days a week with the various supplies needed as they visited up to 4 ETU sites to prepare the ZMapp at the site, await information on any AEs, and collect case report forms (Figures 1 and 2). The ETUs were spread out over a 90-mile radius and could be de-

scribed as austere platforms for health care delivery.

An additional challenge was dealing with the multinational organizations that staffed the various ETUs. Relief organizations from Italy, the United Kingdom, China, as well as the Sierra Leone military provided the staffing for the 4 ETUs. Regardless of who operated the ETU, the concept of randomization to ZMapp or standard of care required significant tact and diplomacy in communicating the scientific necessity in order to appropriately answer the research question. As Davey and colleagues pointed out, the randomized, controlled trial established the appropriate ethical framework to determine whether the research intervention was associated with harmful effects as there had not been a phase 1 safety study with the drug.¹³

As the summer approached in Sierra Leone, the team worked through challenges in the IV administration of ZMapp as the protein structure of the monoclonal antibody had not previously been subjected to West African environmental extremes. A balance between speed of administration to prevent protein aggregation in the heat as opposed to the risk of infusion reactions from a foreign protein required the team to communicate frequently with, the manufacturer of ZMapp, to establish realistic infusion rate tables. Additionally, as the various deployment teams rotated in and out, procedures for establishing continuity of research operations were enacted and improved on with each rotation. Good documentation practices to adequately collect all required study information (eg, recording AEs, deviations, and signatures on various forms) proved critical to continuity of research operations.

In Guinea, not only was there the new wrinkle of working within

a country where the primary language was French, but also a French cosponsor, Inserm. The NIAID clinical director capitalized on the research infrastructure established for a recently completed Inserm study of favipiravir in the treatment of Ebola to extend the ZMapp study to Guinea. Fortunately, many of the Inserm staff were bilingual and readily responded to the NIH training on the requirements of the ZMapp protocol. However, procedures for cold-chain storage and transportation needed to be established. In Guinea, the PHS officers were key in establishing access and temperature monitoring procedures for a secure room inside the U.S. embassy. The issues associated with cold-chain procedures in the infrastructure-limited environments of West Africa are substantial and warrant consideration of a stand-alone paper. Corps officers also took part in weekly country-focused team meetings with embassy staff to describe progress with the ZMapp study.

As the epidemic waned and NIH transitioned to the survivor and viral persistence studies, the operational tempo changed to allow Corps officers to take part in more definitive capacity building efforts. An initial PHS volunteer from the FDA accepted a position within NIAID as a clinical research oversight manager for pharmacy operations. This individual deployed on numerous occasions to the 3 affected West African countries to further establish cold-chain processes for pharmaceuticals and biologics. He also worked with a multidisciplinary team to renovate a clinical research facility in a rural setting in Guinea. In Liberia, he coordinated an effort with other Corps officers to provide educational seminars on clinical research principles and drug-specific topics with

the University of Liberia School of Pharmacy.

CHALLENGES

In each instance, the partnership experience was not without a few problems. The match of skills between the officers who wanted to help and those needed for the research program did not always coincide. While the Corps has more than 1,200 pharmacy officers on active duty, only a fraction of those have experience conducting FDA-regulated clinical research.

Communication problems and time pressures were also constant companions to both the Corps and the NIH. The Corps was going through the largest international deployment in its history to staff multiple missions (including the primary MMU mission in Liberia). The addition of the NIH partnership, while consistent with the MMU staffing mission, provided even more work for a very limited resource. Communicating to the many Corps officers who wanted to volunteer and keeping deployment time lines on track were a challenge. Complicating the matter was the addition of stray e-mails from well-intentioned NIH and Corps staff who communicated directly with colleagues to encourage participation, not fully understanding the policies and protocol governing the deployment process.

Time was always an issue as the rotation schedules were relatively short and the number of activities to make an officer deployment ready were numerous. Obtaining official passports and visas was a challenge as that activity required coordination with the U.S. Department of State. Airline schedules changed with little or no notice, complicating deployments and returns. As the NIH added additional research studies for which

support was required, time lines for studies to start became difficult to predict with certainty due to factors outside the control of the NIH. Recently, additional security training requirements for government workers traveling abroad were instituted, further complicating the process of deploying an officer.

The Corps officers taking part in this research response (which was not consistent with customary deployments from Corps headquarters) necessarily were volunteers from full-time assignments within DHHS, and as such, required the permission of their supervisory chain to volunteer. Regardless of this limitation, there was widespread support for these additional and specific research deployments. Although the use of short-term rotations was not ideal, in the end, the rotation plans worked, and the NIH was able to fulfill its research mission with the support of the Corps.

LESSONS LEARNED/PREPARING FOR THE FUTURE

Many lessons have been learned and continue to be learned throughout this research response and NIH/Corps partnership. Effective and frequent communication between the organization requesting Corps officers and the Corps headquarters is crucial. In the initial deployments, officers were deployed from the FDA with the assumption that they would be familiar with FDA-regulated clinical research. This was not always the case. The NIH and Corps headquarters later collaborated to develop a survey to send to Corps officers that was used to identify specific skill sets needed by officers who would be deploying to conduct clinical research. NIH personnel pre-screened survey responses to identify and prioritize officers for deployment

consideration by the deployment authority. This process resulted in the selection of officers who generally needed less training and guidance.

Effective training in clinical research principles for deployed officers and other staff needs to be developed and made available to all deploying individuals. All clinical research staff are required to have training on GCP, but most GCP training programs focus primarily on the ethical principles of research as outlined by the Declaration of Helsinki, Nuremberg Code, and other documents. Few GCP training programs present adequate information on the hands-on conduct of clinical research, especially research regulated by the FDA and other government bodies and therefore subject to certain strict requirements. Examples of crucial but often overlooked topics are source document retention, good documentation practices, cold-chain principles, and other issues related to the creation and retention of adequate trial records.²¹

The handoff between returning and deploying officers is crucial. Due to various issues with changing time lines, flights, and administrative processes, it is imperative to plan adequate overlap between returning and deploying officers. Delays in obtaining passports or visas, flight cancellations, and other unforeseen issues may unexpectedly shorten any planned overlap periods. A full workweek is desirable for overlap so that the new officer may experience tasks that occur throughout the week, be introduced to the various team members, and have help if unexpected events occur. A regular staff member should check periodically that proper procedures are being followed, as some information may be missed during each handoff, and

consecutive unchecked handoffs could result in large deviations of important procedures. Onboarding and offboarding checklists should be developed and updated regularly to guide the handoff process.

On a larger scale, the respective agencies and other stakeholders involved in planning clinical research for public health emergencies need to be included in regular tabletop training exercises to better understand how to coordinate a response when needed. Additionally, although many of the Corps officers who took part in this deployment served as mentors for others preparing for deployment, establishing a formal roster of experienced officers to support specific roles of this type of response would help serve as a resource center for future deployments. Finally, coordination between any operating division (or agency) and the Corps should be through the established Corps command infrastructure to eliminate miscommunication and complicating deployment processes.²²

CONCLUSION

The increasing connectedness of this world, as demonstrated by the Ebola epidemic, requires that the HHS engage globally to provide international leadership and technical expertise in science, policy, and programs and work in concert with interagency partners.²³ The missions of the PHS and NIH intersected in a synergistic manner in the research response to the Ebola epidemic of 2014-2016. The PHS Corps mission includes to “protect, promote, and advance the health and safety of the Nation...through rapid and effective response...and advancement of public health science.”²⁴ The Corps mission directly supported the NIH mission to seek fundamental knowledge about the nature and

behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.²⁵

The scope and scale of DHHS’s response to the Ebola epidemic was unprecedented. The NIH research program, although successful and an important component, was but a small part in bringing the Ebola crisis to an end. The CDC (including the many Corps officers assigned to that agency) worked successfully with the international community and the host countries to bring the disease under control. The Biological Advanced Research and Development Authority provided expert project management, making vaccines and therapeutics available for research.

The DoD was a partner in the development of countermeasures and phase 1 clinical research programs as well as establishing laboratory facilities in Liberia. The Department of State facilitated the many interactions required for the mobilization of resources into West Africa. The collective efforts of the U.S. government contributed immensely to the protection of U.S. borders and to the successful resolution of the Ebola outbreak of 2014-2016. ●

Author disclosures

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