

## Ebola vaccine trials: the role of eHealth

The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) enabled CDC to coordinate the activities of several hundred health staff, despite the terribly difficult circumstances

Since the height of the 2014-2016 West African Ebola outbreak and response, eHealth Africa (eHA) has worked with West African Ministries of Health (MOHs) to rigorously improve emergency management operations, electronic disease reporting systems, and laboratory and diagnostic systems. eHA's progress in Sierra Leone has gone a step further and strengthened the global Ebola research base through managing clinical trials and building partnerships with donors and local institutions to strengthen local healthcare capacity.

Healthcare workers and frontline workers are at an elevated risk for contracting Ebola during an Ebola outbreak because their work involves handling infectious blood and secretions. These high-risk occupations include doctors and nurses, and expand to include burial workers, ambulance teams, health facility staff, surveillance teams, and others working on the frontline.

During the course of the 2014-2016 outbreak, there were over 850 confirmed health worker infections reported across Guinea, Liberia, and Sierra Leone, including over 500 reported deaths. High infection rates are contributed to by the Sierra Leonean healthcare context including challenges with following infection prevention control protocols and insufficient amounts of appropriate personal protective equipment.

There were no Food and Drug Administration of the United States (FDA) approved vaccines or medicines available to prevent or treat Ebola prior to the West African Ebola outbreak. Thus, a clinical trial was needed to both test Ebola vaccines and distribute effective vaccines to the populations most at risk. Thus, the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) expanded the safety and immune information of rVSV-ZEBOV candidate Ebola vaccine gained from previous studies into a Phase 2 and Phase 3 clinical trial. STRIVE was implemented during the Ebola epidemic to allow healthcare workers to both have access to this unlicensed vaccine and also to serve as a mechanism to monitor those vaccinated for side effects.

Through STRIVE, eHA and partners enrolled and vaccinated over 8,000 healthcare workers and frontline workers against Ebola in Sierra Leone. In order to accomplish the feat, it established a nation-wide team of logisticians, district officers, call center staff, medical personnel and project management staff. eHA served as the Center for Disease Control and Prevention's (CDC) major contracted partner in executing STRIVE en-



abling it and leveraged partners, to subcontract clinical activities and supervision to the Sierra Leone College of Medicine and Allied Health Sciences (COMAHS). COMAHS provided over 350 clinical staff for the trial.

eHA served as the operational backbone of the trial, overseeing the logistics of the trial and supplying eight vaccination sites with trained staff. STRIVE worked to establish a national supply chain of the Ebola vaccine, and its extensive cold chain support extended to the most remote of the eight vaccination sites.

eHA adapted software and digital tools developed for the outbreak to the needs of STRIVE, allowing near real-time monitoring of participants' medical experience following vaccinations. This included building a network of public and private partnerships to create a national medical insurance scheme for participants. This scheme was linked to the 711 hotline, an independent call center open 24-hours per day staffed by eHA for STRIVE participants. Additional digital tools created included the establishment of an online patient registration tool with mobile payment services.

STRIVE continued through August of 2017 in order to conduct follow-up for its over 8,000 vaccine trial participants. This follow-up included tracking adverse events and the presence of Ebola and treating any serious adverse events and acute medical conditions.

Ultimately, STRIVE's success was measured by eHA's ability to enroll, vaccinate and monitor enough participants for the evidence to contribute to licensure of a vaccine against Ebola. This trial's timely and strategic execution meant that a large portion the Sierra Leonean workforce most at risk for contracting Ebola received a vaccination. eHA is proud of their completion of Sierra Leone's largest clinical trial, especially because it was executed during both an emergency response and a national state of emergency.

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