The Journal of Infectious Diseases

SUPPLEMENT ARTICLE

Health Conditions in an Adult Population in Sierra Leone: Data Reported From the Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE)

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The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE), a clinical trial of the investigational recombinant vesicular stomatitis virus–based Ebola virus vaccine (rVSVΔZEBOV-GP; Merck), provided an opportunity to assess health conditions in a cohort of healthy Sierra Leonean adults before vaccination. Of the 8793 healthcare and frontline Ebola response workers screened for study enrollment, 7 (0.1%) self-reported human immunodeficiency virus infection or another significant immunodeficiency disorder and 11 of 3190 (0.3%) women 18–49 years old had a positive urine pregnancy test. Of the 440 participants included in a safety substudy, 124 (28.2%) reported at least 1 medical condition at baseline, most commonly drug hypersensitivity (11.6%), arthralgia (3.9%), arthropathy (2.7%), or gastric (3.0%) or peptic (2.7%) ulcer disease. We calculated the incidence per 100 person-years (PY) and 95% confidence intervals (CIs) of new medical conditions among the 4297 participants followed for 18–24 weeks from enrollment to scheduled vaccination. The most commonly reported conditions were headache (32.4 PY [95% CI, 29.7–35.3 PY]), pain (unspecified) (17.3 PY [95% CI, 15.4–19.4 PY]), arthralgia (9.3 PY [95% CI, 7.9–10.8 PY]), and abdominal pain (9.1 PY [95% CI, 7.7–10.7 PY]). Nasopharyngitis (7.0 PY [95% CI, 5.8–8.4 PY]) and malaria (1.9 PY [95% CI, 1.3–2.7 PY]) were the most commonly reported infectious conditions. Several cases of hypertension, diabetes mellitus, and cancer were also reported.

Clinical Trials Registration. ClinicalTrials.gov [NCT02378753] and Pan African Clinical Trials Registry [PACTR201502001037220].

Keywords. health conditions; disease burden; Sierra Leone; Ebola; Ebola vaccine.

Little information is available about the burden of infectious or noninfectious diseases in Sierra Leone, especially among adults. Life expectancy at birth is 50 years, one of the lowest in the world, and the maternal mortality ratio is 1360 per 100 000 births, one of the highest [1]. Malaria is one of the most serious public health problems and contributes to an estimated 25% of all-age mortality [1]. Noncommunicable diseases account for an estimated 18% of all deaths in Sierra Leone, and a recent report from the Sierra Leone Ministry of Health and Sanitation suggests that the prevalence of noncommunicable diseases (diabetes mellitus; cardiovascular disease, including hypertension and stroke; and cancer) is increasing [2]. A better understanding of common medical conditions in Sierra Leone would help the country prioritize public health and clinical medical programs.

In response to the 2014–2016 Ebola virus disease (Ebola) outbreak that affected >28 000 people and claimed >11 000 lives, mostly in Guinea, Sierra Leone, and Liberia [3], the United States Centers for Disease Control and Prevention (CDC) sponsored a clinical trial of an investigational Ebola vaccine in Sierra Leone. The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) was a partnership between the College of Medicine and Allied Health Sciences, University of Sierra Leone, Ministry of Health and Sanitation, and CDC [4]. The primary objectives of the trial were to evaluate the safety and efficacy of the recombinant vesicular stomatitis virus–based Ebola virus vaccine (rVSVΔZEBOV-GP; Merck Pharmaceuticals) in an adult population. Because we collected basic health information as part of the trial, STRIVE provided a unique opportunity to assess health conditions in a cohort of generally healthy Sierra Leone healthcare and frontline Ebola response workers.

METHODS

Main Study Design

The main study has been described previously in detail [5]. In brief, the study was an unblinded trial with participants

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Presented in part: IDWeek; New Orleans, LA; 26–30 October 2016. Abstract 748.

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The Journal of Infectious Diseases® 2018;217(S1):S75–80

DOI: 10.1093/infdis/jix603

individually randomized to either immediate (within 7 days of enrollment) or deferred (18–24 weeks from enrollment) vaccination. No placebo was used. Eligible participants included healthcare and selected Ebola frontline workers who were ≥18 years old and resided in selected chiefdoms in the 5 study districts. The study staff screened potential participants to ensure they met study eligibility criteria and then enrolled them in the study, randomizing them to either immediate or deferred vaccination groups. The first approximately 400 participants (~5% of the total participants) enrolled in the main study had the opportunity to participate in an enhanced safety substudy [5]. STRIVE staff members collected baseline health information at each step in the screening, main study enrollment, and safety substudy enrollment process using standardized data collection forms. Baseline health information was self-reported by the study participant; health records were not reviewed.

Once enrolled, STRIVE staff members followed all participants for 6 months postvaccination to evaluate vaccine safety; those in the deferred group were also followed from enrollment to vaccination. The staff made monthly telephone calls to participants to monitor their health, and a STRIVE telephone hotline was available to participants 24 hours a day for reporting incident medical issues [6]. Participants reporting a new medical issue were referred to a STRIVE study nurse who made the initial assessment of the participant's condition. The nurse followed the participant by telephone until resolution of the condition or referred the participant immediately or during follow-up to a study physician, as appropriate. Physicians primarily used clinical evaluation to make diagnoses unless the illness was severe or the participant was hospitalized; there was limited availability of laboratory and radiologic diagnostic tools. For participants who were evaluated by a study physician or hospitalized, medical records were reviewed. Study enrollees received free medical care for the duration of their participation in the study in designated study clinics and hospitals.

All STRIVE study staff spoke fluent English, the official language of Sierra Leone, and Krio (an English-based Creole language), the most common local language. Data collection forms were in English as Krio is mainly a spoken language. Interviews with participants were conducted in English or Krio, as needed.

Data Collection

For this descriptive study, we analyzed self-reported medical information at baseline from all STRIVE participants including more detailed information collected from the subset of participants enrolled in the safety substudy. We also analyzed newly reported medical events that occurred during the trial in the deferred participants before they were vaccinated.

For the baseline analysis, we examined data collected as follows. First, at screening, all potential participants were asked to report human immunodeficiency virus (HIV) or other immunodeficiency conditions; women 18–49 years old were asked if they were pregnant and all underwent a urine pregnancy test. Both HIV infection/immunodeficiency and pregnancy excluded potential participants from study enrollment. Second, following screening, at enrollment, we collected participant demographics and medical information on allergies and history of arthritis or other joint problems; concerns about vaccine-associated arthritis were raised in a phase 1 study of this vaccine [7]. Third, we asked participants in the safety substudy group additional open-ended questions to obtain more detailed information regarding serious or chronic health conditions and current medication use that could potentially impact interpretation of the safety substudy data. We did not ask specifically about herbal or natural remedies or preparations from a healer.

For the analysis of incident events occurring during the trial, we limited the analysis to participants randomized to the deferred vaccination group (hereafter referred to as the unvaccinated group). We describe new medical events or conditions reported by these participants as they were followed prospectively during the 18–24 weeks from enrollment to vaccination. Participants who were inadvertently vaccinated with the immediate group or had no safety follow-up were excluded from this analysis.

Medical events and conditions were coded using the Medical Dictionary for Regulatory Activities (MedDRA), the international medical terminology developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; MedDRA system organ class (SOC) and preferred term (PT) are reported. Symptoms were reported individually if a single unifying diagnosis was not available.

For baseline conditions in the substudy participants, we report all SOCs and, within each SOC, the PTs reported by >1% of participants. In the prospective analysis in the unvaccinated group, we report the 5 most common SOCs and the 3 most common PTs within each SOC. In this group we also report data on selected noncommunicable diseases of interest (hypertension, diabetes mellitus, cancer, cardiovascular disease, and stroke) [2].

Statistical Methods

Prevalence is reported for demographics and conditions collected at baseline. For the unvaccinated group, the incidence of the most common newly reported medical conditions is presented in person-years (PY) with 95% confidence intervals (CIs) to account for the varying follow-up times. We computed CIs for incidence rates using the gamma distribution, of which the Poisson distribution is a member, to determine upper and lower limits of the number of events. Comparisons were made using a χ^2 test for categorical characteristics or a Student t test for continuous characteristics. All hypothesis tests were done using 2-sided tests at a 5% significance level.

Ethical Approval and Informed Consent

Prior to beginning STRIVE, ethical and regulatory approvals were obtained from the Sierra Leone Ethics and Scientific Review Committee, CDC Institutional Review Board, Pharmacy Board of Sierra Leone, and US Food and Drug Administration. Written informed consent was obtained from all participants and the study was conducted according to Good Clinical Practices.

RESULTS

Overall Results

Overall, 8815 potential study participants were assessed for eligibility; 22 participants were later found to have invalid documentation of consent and their data were excluded from the analysis. Of the remaining 8793 potential participants who underwent the initial screening, 7 (0.1%) reported HIV infection or another significant immunodeficiency disorder (details not specified) and 11 of 3190 (0.3%) women 18–49 years old, none of whom self-reported being pregnant, had a positive urine pregnancy test and were excluded from enrollment. An additional 124 potential participants were excluded for other reasons [5]. The remaining 8651 were randomized and comprised the baseline assessment group. Of these, 440 were enrolled in the safety substudy. There were 4297 unvaccinated participants followed prospectively from enrollment to scheduled vaccination for new health conditions.

Baseline Demographics Among All Enrolled Participants

The median age of the 8651 participants in the baseline assessment group was 30.7 years (range, 18.0–79.5 years); 60.6% were male (Table 1). The majority (85.8%) of participants had at least a secondary or tertiary education; 8.6% reported having no education. At enrollment, most participants were working as Ebola frontline workers (48.1%) or nurses (33.3%).

Prevalence of Baseline Allergies, Arthritis, and Joint Problems Among All Enrolled Participants

Of the 8651 participants, 740 (8.6%) reported a history of arthritis or other joint problem. The majority reported a PT of arthralgia (3.6%) or arthropathy (2.9%); 0.3% reported a PT of arthritis. These participants tended to be older and were more likely to be female than participants who did not report these conditions (median age, 37.2 vs 30.3 years; 47.8% vs 38.6% female: $P < .0001$ for both comparisons). There were no statistically significant differences in other demographic characteristics between those who did and did not report a history of arthritis or other joint problem. Among the 1219 (14.1%) participants who reported a history of any allergic reaction, 1137 (93.3%) reported a drug hypersensitivity, most commonly (>60.0%) to an antimalarial medication.

Table 1. Enrolled Participant Demographics, Sierra Leone Trial to Introduce a Vaccine Against Ebola (N = 8651)

Characteristic	No. (%)
Age, y, median (range)	30.7 (18.0–79.5)
Sex	
Female	3407 (39.4)
Male	5244 (60.6)
Primary occupation	
Nurse[a]	2877 (33.3)
Doctor	25 (0.3)
Allied health professional[b]	149 (1.7)
Pharmacist	40 (0.5)
Community health worker	178 (2.1)
Laboratory worker	273 (3.2)
Frontline response worker	4166 (48.2)
Surveillance worker	500 (5.8)
Other/not reported	443 (5.1)
District of residency	
Western area urban	3867 (44.7)
Western area rural	1277 (14.8)
Port Loko	1568 (18.1)
Bombali	1209 (14.0)
Tonkolili	729 (8.4)
Other	1 (<0.1)
Education	
None	740 (8.6)
Primary	451 (5.2)
Secondary	3823 (44.2)
Tertiary	3595 (41.6)
Other/not reported	42 (<0.1)

Data are presented as No. (%) unless otherwise indicated.

[a]Nurse, nurse aide, maternal child health aide, nursing student, midwife, community health nurse, vaccinator.

[b]Dentist, nutritionist, medical counselor, physiotherapist.

Prevalence of Baseline Medical Conditions and Medication Use Among Safety Substudy Participants

Of the 440 participants enrolled in the safety substudy, 124 (28.2%) reported at least 1 serious or chronic medical condition; 37 (30.3%) of these reported >1 condition. Drug hypersensitivity was the most commonly reported medical condition (11.6%) (Table 2). Arthralgia or arthropathy was reported by 3.9% and 2.7% of participants, respectively; other joint conditions were reported by 2.7%. Gastric ulcer was reported by 3.0% and peptic ulcer by 2.7%; an additional 1.8% of participants reported having an ulcer, but the site (eg, gastrointestinal, skin, other) was not recorded. Malaria was reported by 1.4% of participants and typhoid fever by 1.1%. One hundred seventeen of these 440 participants (26.6%) reported taking any medication at the time of enrollment. The most commonly reported medications among these 440 participants were analgesics (10.7%), antimalarials (9.5%), antibacterials (7.0%), drugs for gastrointestinal acid–related disorders (2.7%), contraceptives (6.9% of 145 women 18–49 years of age), and anti-inflammatory drugs

Table 2. Baseline Medical Conditions Reported by Safety Substudy Participants by Medical Dictionary for Regulatory Activities System Organ Class (n = 440)

MedDRA SOC and PT[a]	No.	(%)
Congenital, familial, and genetic disorders	4	(0.9)
Eye disorders	2	(0.4)
Gastrointestinal disorders	26	(5.9)
Gastric ulcer	13	(3.0)
Peptic ulcer	12	(2.7)
Other	1	(0.2)
General disorders and administration site conditions	10	(2.3)
Ulcer[b]	8	(1.8)
Other	2	(0.4)
Hepatobiliary disorders	1	(0.2)
Immune system disorders	62	(14.1)
Drug hypersensitivity	51	(11.6)
Food allergy	6	(1.4)
Other	5	(1.1)
Infections and infestations[c]	13	(3.0)
Malaria	6	(1.4)
Typhoid fever	5	(1.1)
Other	3	(0.6)
Injury, poisoning, and procedural complications	3	(0.7)
Investigations	1	(0.2)
Musculoskeletal and connective tissue disorders[c]	39	(8.9)
Arthralgia	17	(3.9)
Arthropathy	12	(2.7)
Other	12	(2.7)
Nervous system disorders	2	(0.5)
Respiratory, thoracic, and mediastinal disorders	3	(0.7)
Surgical and medical procedures	1	(0.2)
Vascular disorders	1	(0.2)

Abbreviations: MedDRA, Medical Dictionary for Regulatory Activities; PT, preferred term; SOC, system organ class.

[a]Within each SOC, individual PTs reported by ≥1% of substudy participants are listed.

[b]The organ system affected was not documented.

[c]The sum of the PTs is greater than the total for the SOC because some participants in this SOC reported >1 PT.

(1.8%). No participant reported diabetes, hypertension, cardiovascular disease, or cancer.

Incident Medical Events in the Unvaccinated Group

Among the 4297 unvaccinated participants, 1020 (23.7%) reported 3123 new medical events during the time period of interest. The 5 most commonly reported MedDRA SOCs were general disorders and administration site conditions (51.6 per 100 PY [95% CI, 48.2–55.2 PY]), nervous system disorders (36.4 per 100 PY [95% CI, 33.5–39.4 PY]), musculoskeletal and connective tissue disorders (27.0 per 100 PY [95% CI, 24.6–29.6 PY]), gastrointestinal disorders (23.1 per 100 PY [95% CI, 20.9–25.6 PY]), and infections and infestations (12.7 per 100 PY [95% CI, 11.0–14.5 PY]) (Table 3). The most commonly reported medical condition in these SOCs was headache (32.4 per 100 PY), followed by pain (site unspecified) (17.3 per 100 PY), arthralgia (9.3 per 100 PY), and abdominal pain (9.1 per 100 PY). In the infections and infestations SOC, nasopharyngitis (ie, upper respiratory tract infection) (7.0 per 100 PY [95% CI, 5.8–8.4 PY]) and malaria (1.9 per 100 PY [95% CI, 1.3–2.7 PY]) were the most commonly reported conditions.

Table 3. Incidence of Reported Medical Conditions in the Deferred Group by the 5 Most Common Medical Dictionary for Regulatory Activities System Organ Classes and 3 Most Common Preferred Terms

MedDRA System Organ Class/ Preferred Term	Incidence per 100 PY (95% CI) (n = 4297; PY = 1663.863)
Gastrointestinal disorders	23.1 (20.9–25.6)
Abdominal pain	9.1 (7.7–10.7)
Toothache	2.1 (1.5–3.0)
Abdominal pain upper	1.8 (1.2–2.6)
General disorders	51.6 (48.2–55.2)
Pain (unspecified)	17.3 (15.4–19.4)
Pyrexia	8.8 (7.5–10.4)
Feeling hot	7.6 (6.3–9.0)
Infections and infestations	12.7 (11.0–14.5)
Nasopharyngitis	7.0 (5.8–8.4)
Malaria	1.9 (1.3–2.7)
Furuncle	0.8 (.4–1.3)
Musculoskeletal and connective tissue disorders	27.0 (24.6–29.6)
Arthralgia	9. 3 (7.9–10.8)
Flank pain	6.0 (4.9–7.3)
Myalgia	4.3 (3.3–5.4)
Nervous system disorders	36.4 (33.5–39.4)
Headache	32.4 (29.7–35.3)
Dizziness	3.4 (2.6–4.4)
Dysgeusia[a]	0.2 (.0–.5)

Abbreviations: CI, confidence interval; MedDRA, Medical Dictionary for Regulatory Activities; PY, person-years.

[a]Distortion of sense of taste.

When the medical events coded to a PT of hypertension or blood pressure increase were combined, the incidence was 0.4 per 100 PY (95% CI, .1–.8 PY). The incidence of diabetes mellitus was 0.2 per 100 PY (95% CI, .0–.5 PY). Three types of cancer were reported (chronic myeloid leukemia, hepatocellular carcinoma, and nasopharyngeal carcinoma), each with an incidence of 0.1 per 100 PY (95% CI, .0–.3). There were no reports of cardiovascular disease or stroke.

DISCUSSION

STRIVE provided a unique opportunity to assess selected aspects of the general health status of an adult population in Sierra Leone, a country for which there is a paucity of health data. Our data provide new insight into common infectious and noninfectious medical conditions in this population in Sierra Leone, as well as point out gaps in knowledge.

The prevalence of self-reported HIV infection was 0.1% in the cohort screened for STRIVE enrollment, much lower than the United Nations 2014 estimate of 1.4% (1.2%–1.6%) among Sierra Leone adults [8]. While this may be because our study

population primarily consisted of healthcare workers who had high educational and medical knowledge levels, it may also underrepresent the true prevalence. Study participants screened for enrollment may not have reported HIV infection because of fear of stigma, or because they wanted to participate in the study and knew HIV infection would exclude them. An illustrative example was the diagnostic workup for an acute illness in a study participant that revealed HIV infection of unknown duration but likely not of acute onset, which was not reported at enrollment. In STRIVE, none of the 11 women who were excluded from enrollment because of a positive pregnancy test self-reported being pregnant. This highlights the importance of testing for pregnancy if it is an exclusion criterion.

A history of joint problems, which was associated with older median age and being female, was reported by 8.6% of enrolled participants. This prevalence was lower than the prevalence of chronic joint symptoms reported by a similarly aged (18–44 years old) cohort in the United States (17%) [9]. It was also lower than the prevalence of osteoarthritis reported from 3 of 4 studies described in a summary of arthritis studies in Africa (0.4%, 29.5%, 29.7%, and 77.2%), but those populations were older than the STRIVE population [10]. Similar to ours, these studies and another from Nigeria [11] found that joint conditions were associated with being female.

Peptic ulcer disease was commonly reported by the substudy participants at enrollment, but it is not clear if the diagnosis reflects true peptic ulcer disease or a broader range of conditions that present with abdominal pain, dyspepsia, or other upper gastrointestinal symptoms. Additionally, abdominal pain was among the most commonly reported incident medical conditions in the unvaccinated group. In Sierra Leone, anecdotal reports suggest that people who present as outpatients with any type of upper gastrointestinal complaint are often given a diagnosis of peptic ulcer disease and treated empirically. This is consistent with our finding that almost 3.0% of the substudy population reported taking a medication for gastrointestinal acid–related disorders at the time of enrollment. A better understanding of the prevalence of true peptic ulcer disease in Sierra Leone could help determine whether there is overuse of these medications or if empiric treatment for peptic ulcer disease of patients presenting with certain types of abdominal pain might be warranted.

The observed incidence of malaria is consistent with Sierra Leone having one of the highest rates of malaria in the world [12]. While the impact of malaria on health is greatest among children, our data underscore its heavy toll on adult health as well. The seasonal pattern of malaria in our study, with the majority of cases reported during the rainy season (data not shown), is consistent with a previously published study showing the highest cumulative case counts of malaria during May through August [13]. However, it was difficult to estimate the true burden of malaria from our study. Not all cases of malaria were laboratory confirmed and participants with a febrile illness may have been misdiagnosed as having malaria. Also, a participant who reported a single symptom or a combination of symptoms associated with malaria, such as headache, fever, malaise, or joint pain, rather than a unifying diagnosis of malaria, would not have been recorded as having malaria. In the main STRIVE study, we actively sought a unifying diagnosis for all serious medical events, but that was not feasible for less serious medical events [5, 14].

Headache was one of the most commonly reported incident conditions. We did not determine the underlying causes of headaches, but in a case series of 250 patients with headaches in Sierra Leone, migraine and tension headaches were the most common; hypertension accounted for only 4% of headaches [15].

New reports of hypertension and diabetes mellitus were reported by some STRIVE participants during the follow-up period. The estimates of 0.4 (hypertension) and 0.2 (diabetes mellitus) cases per 100 person-years may overestimate incident cases because the provision of medical care by STRIVE may have led to the detection of prevalent cases; routine preventive medical screening is not common in Sierra Leone for adults. Also, some participants may have been aware of their diagnosis before participating in STRIVE, but we did not routinely capture this information at enrollment. However, these data, along with World Health Organization age-adjusted estimates for raised blood pressure (24.9%) and raised blood glucose (8.0%) in Sierra Leonean adults, suggest a substantial burden of these diseases in the population [16, 17]. Some new cancer diagnoses were also reported in our cohort, though cancer diagnostics are limited in Sierra Leone.

More than 25% of this relatively young adult population reported taking a medication at the time of enrollment, most commonly an analgesic, antimalarial, or antibacterial. We did not elicit information regarding who prescribed the medication or the reason for taking it. However, in a study of antimicrobial use among Sierra Leonean university students, 70% reported taking a medication that was not prescribed by a physician [18]. In that study, the most common indications for dispensing the medication were a cold or diarrhea, but they were also dispensed for sexually transmitted infections, malaria, and typhoid fever. These data underscore the need for diagnosis-directed treatment and, in an era of global concern about increasing antimicrobial resistance, a better understanding of antimicrobial prescribing use and promotion of their judicious use in Sierra Leone [19, 20].

In our study cohort, 13.1% of participants reported drug hypersensitivity, which was lower than the percentage found in a similar population in Mozambique. In that study, 25% of university students and nonteaching staff members reported a drug allergy, with most attributed to chloroquine, β-lactams, cotrimoxazole, and aspirin [19]. In a US study, the prevalence of self-reported drug allergy recorded in the medical records in a large outpatient population was 22.4%; antibiotics accounted for slightly more than half of the reports [21].

The data we report should be interpreted in the context of the study limitations. The study population is not representative of the

general population of Sierra Leone because of the high proportion of participants who were healthcare workers, who tend to be more highly educated and socioeconomically advantaged than the general population [22]. For the baseline data, except for the urine pregnancy test, all medical conditions were self-reported and they were sometimes reported and coded as a symptom or group of symptoms, without a unifying diagnosis. Also, because there is no routine preventive screening in Sierra Leone, we likely underestimated certain conditions, especially chronic conditions that may be asymptomatic (eg,, hypertension, diabetes). The intent of collecting additional health information from the substudy participants was to capture current chronic or serious illnesses. However, some of these participants may have also reported past illness. In the unvaccinated group followed for incident conditions, we relied on monthly calls to the participants and passive participant reporting to the study hotline. Although participant follow-up with the monthly telephone calls was high [23], it is possible that reporting was incomplete. The lack of diagnostic capacity in Sierra Leone limited diagnosis of some medical conditions.

Despite these limitations, our findings represent a step forward in understanding health conditions affecting adults in Sierra Leone and can inform more in-depth studies on disease burden and etiology, which could be used to guide clinical and public health services.

Notes

Acknowledgments. We are grateful to STRIVE staff members for their work and dedication to the study and STRIVE participants for their willingness to participate in the study. We also thank Linda Elsner, Ana Choban, and Christina Ottis for assistance in preparing the manuscript.

Disclaimer. The findings and conclusions in this report are those of the author(s) and do not necessarily represent the official position of the CDC.

Financial support. The trial was funded by the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, and the National Institutes of Health, with additional support from the CDC Foundation.

Supplement sponsorship. This work is part of a supplement sponsored by the Centers for Disease Control and Prevention.

Potential conflicts of interest. J. E.-K., P. D., and R. L. report grants from BARDA during the conduct of the study. All other authors report no potential conflicts. All authors have submitted the ICJME Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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