



DHS First Responder Vaccine Initiative Pilot Program

June 3, 2021

Annual Report to Congress



Homeland
Security

*Countering Weapons of
Mass Destruction Office*

Message from the Secretary for Homeland Security

The following annual report, *DHS First Responder Vaccine Initiative (FRVJ) Pilot Program*, has been prepared by the U.S. Department of Homeland Security Countering Weapons of Mass Destruction Office in conjunction with the U.S. Department of Health and Human Services Assistant Secretary for Preparedness and Response.

This document was compiled pursuant to a requirement in the First Responder Anthrax Preparedness Act (Pub. L. No. 114-268) 42 U.S.C. § 247d-6b note. Included is an overview of that requirement.

This report is submitted to the following Members of Congress:

The Honorable Bennie G. Thompson
Chairman, House Committee on Homeland Security

The Honorable John Katko
Ranking Member, House Committee on Homeland Security

The Honorable Frank Pallone
Chairman, House Committee on Energy & Commerce

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on Energy & Commerce

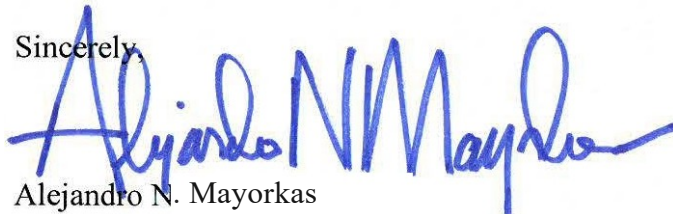
The Honorable Gary C. Peters
Chairman, Senate Committee on Homeland Security and Governmental Affairs

The Honorable Rob Portman
Ranking Member, Senate Committee on Homeland Security and Governmental Affairs

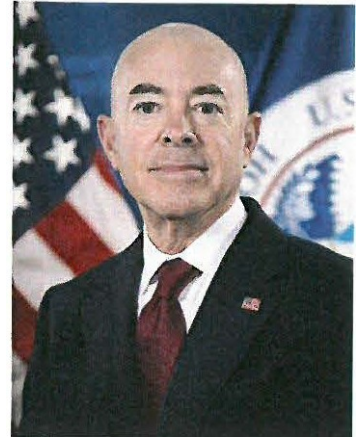
The Honorable Patty Murray
Chairman, Senate Committee on Health, Education, Labor, and Pensions

The Honorable Richard Burr
Ranking Member, Senate Committee on Health, Education, Labor and Pensions

Sincerely,



Alejandro N. Mayorkas
Secretary



Executive Summary

This report fulfills requirements contained in Public Law 114-268, 42 U.S.C. § 247d-6b note, The First Responder Anthrax Preparedness Act (the Act), for the Secretary of the Department of Homeland Security, in conjunction with the Secretary of the Department of Health and Human Services, to submit to Congress a report on the progress and results of the First Responder Vaccine Initiative (FRVI) Pilot Program. This report is structured to address the specific elements prescribed in Section 2(a)(8)(A) of the Act.

The Department of Homeland Security Countering Weapons of Mass Destruction Office (CWMD), working in conjunction with the Department of Health and Human Services (HHS), is executing the First Responder Vaccine Initiative Pilot that makes anthrax vaccine doses nearing their expiration available on a voluntary basis to state and local emergency response providers for pre-exposure prophylaxis (PrEP) vaccination. CWMD and HHS signed a Memorandum of Understanding (MOU) defining their roles in executing the pilot. In addition, CWMD, working in conjunction with HHS, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), developed an education and training package that informs potential volunteer vaccine recipients from the emergency response provider community about the anthrax threat, the nature of the vaccine program as a preventive countermeasure, and the potential risk-benefit of their involvement with the FRVI Pilot.

CWMD conducted a competitive grant process selecting two sites to conduct the FRVI Pilot. Cooperative Agreement grant awards were made to the city of St. Louis, Missouri, and the State of Mississippi, amounting to a total award of \$980,759 for the conduct of the pilot in their respective jurisdictions, incrementally funded in FY 2019 and FY 2020. In addition to the funds provided to the two participating sites, CWMD and HHS have expended an additional \$119,788 to administer the FRVI Pilot Program to date.

As of September 30, 2020, a total of 1,928 emergency response providers from 55 emergency response agencies were educated under the FRVI Pilot Program, and 1,098 individual emergency response providers volunteered to receive the anthrax vaccine dose series. That schedule includes an initial dose, followed by subsequent doses 30 days after the initial dose and again at 6, 12, and 18 months after the initial dose. Following the conclusion of the main five-dose series, booster doses are required every 3 years to maintain immunity (although the triannual boosters will fall outside of the schedule of the 2-year FRVI Pilot).

Current events have a direct impact on the FRVI Pilot sites. The FRVI Pilot has experienced some delays because of the COVID-19 pandemic as many public health administrators working on the FRVI pilot were diverted to higher priority response duties in their local jurisdictions. CWMD continues to monitor the impact of the COVID-19 pandemic on the Pilot Program while exploring ways the FRVI Pilot infrastructure can positively affect future COVID-19 vaccine distribution efforts. Additionally, response by first responders to civil unrest caused delays and postponement of some training sessions, hindering participation. Participation in the pilot was also affected by the concerns of the International Association of Fire Fighters (IAFF), a national union representing professional firefighters.

A total of 370 vials (3,700 doses) of the anthrax vaccine were released from the Strategic National Stockpile for administration to volunteers and of these, 2,307 doses were administered by September 30, 2020 in accordance with the following breakdown by dose in the vaccination series.

Total Doses Administered as of 30 Sep 2020	Initial	1,053
	30 day	853
	6 month	382
	12 month	4
	18 month	0
	Booster*	15

* These boosters were administered to individuals who had previously completed the 5-dose PrEP vaccination while in the military.

CWMD, HHS, and the two FRVI Pilot sites will continue the FRVI Pilot Program through next year, to include elicitation of additional emergency response provider volunteers. At the end of the Pilot Program period of performance (September 30, 2021), DHS will assess the overall costs and perceived benefits and prepare a recommendation for the advisability of a broad follow-on first-responder vaccine program.



DHS First Responder Vaccine Initiative Pilot Program Annual Report to Congress

Table of Contents

I.	Legislative Language.....	I
II.	Background.....	2
	Purpose.....	2
	Accomplishments of the FRVI Pilot Program.....	3
	Challenges.....	5
III.	Results and Data Report.....	6
	Tabulation of Costs to Administer the Program.....	6
	Number of Eligible Emergency Response Providers and Statistics	7
	Total Vaccine Doses Administered.....	9
IV.	Analysis/Discussion	0
	General Observations.....	11
	Recommendation s to Improve Participation in the Pilot Program.....	11
V.	Conclusion/OHS Action Plan.....	13
	Appendices.....	15
	Appendix A: Certifications.....	15
	Appendix B: List of Acronyms and Abbreviations	16

I. Legislative Language

The First Responder Anthrax Preparedness Act (the Act), Pub. L. No. 114-268), 42 U.S.C. § 247d-6b note, includes the following requirement.

Sec.2(a)(1) The Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall carry out a pilot program to provide eligible anthrax vaccines from the Strategic National Stockpile under section 319F- 2(a) of the Public Health Service Act (42 U.S.C. 247d-6b(a)) that will be nearing the end of their labeled dates of use at the time such vaccines are made available to States for administration to emergency response providers who would be at high risk of exposure to anthrax if such an attack should occur and who voluntarily consent to such administration.

Sec.2(a)(8)(A) Not later than **1** year after the date on which the initial vaccines are administered under this section, and annually thereafter until 1 year after the completion of the pilot program under this section, the Secretary of Homeland Security, in coordination with the Secretary of Health and Human Services, shall submit to the Committee on Homeland Security and the Committee on Energy and Commerce of the House of Representatives and the Committee on Homeland Security and Governmental Affairs and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the progress and results of the pilot program, including-

- (i) a detailed tabulation of the costs to administer the program, including-
 - (I) total costs for management and administration;
 - (II) total costs to ship vaccines;
 - (III) total number of full-time equivalents allocated to the program; and
 - (IV) total costs to the Strategic National Stockpile;
- (ii) the number and percentage of eligible emergency response providers, as determined by each pilot location, that volunteer to participate;
- (iii) the degree to which participants complete the vaccine regimen;
- (iv) the total number of doses of vaccine administered; and
- (v) recommendations to improve initial and recurrent participation in the pilot program.

II. Background

Through the Department of Homeland Security (OHS) Countering Weapons of Mass Destruction Office (CWMD), OHS is executing a First Responder Vaccine Initiative (FRVI) Pilot that has as a primary objective to provide eligible anthrax vaccines from the Strategic National Stockpile (SNS) nearing the end of their labeled date of use to states for voluntary administration to emergency response providers determined to be at high risk of exposure by their respective jurisdiction (as required by their Cooperative Agreement award) and to develop recommendations for the extension of the pilot to a future national-level program . This is being accomplished in operational partnership or coordination with the Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR), Division of the Strategic National Stockpile (SNS).

Purpose

The purpose of the FRVI Pilot is to carry out a pilot program to provide eligible anthrax vaccines from the SNS to selected state and local emergency response providers in order to assess the feasibility for a program to offer vaccinations to emergency responders across the nation who are at high-risk of exposure to anthrax.¹ The FRVI Pilot as a directed exercise is not open-ended. In other words, it does not implement long term sustainment of a First Responder Vaccine Program, but rather identifies applicable procedures and likely costs for such a notional future program. It is intended to identify meaningful recommendations for consideration in continuing a vaccination program beyond the expiration date of the Pilot. To be clear, it is not charged specifically with looking at how the Pilot would scale into a national level program. That said, the Pilot partners are interested in exploring the factors that would be required to implement a broader program. This would include such things as partnering with commercial pharmacy networks nationally, development of FRVI mobile apps for coordination with emergency response providers, development of registries for capturing documentation of vaccines, and connecting those to personal health records systems.

The FRVI Pilot solicits volunteer emergency response providers from state and local agencies that have a role in responding to a potential anthrax attack or incident, draws the necessary vaccine doses from the SNS, and administers the doses according to the vaccine sequence prescribed by the Centers for Disease Control and Prevention (CDC) in accordance with 2019 Advisory Committee on Immunization Practices recommendations.

[https://www.cdc.gov/mmwr/volumes/68/rr/n-6804a1 .htm..](https://www.cdc.gov/mmwr/volumes/68/rr/n-6804a1.htm) That sequence includes an initial dose, followed by subsequent doses 30 days after the initial dose and again at 6, 12, and 18 months after the initial dose.

The CWMD Office oversees the conduct of the pilot, provides the necessary resources to the state and local jurisdictions through competitive Cooperative Agreements, and assesses the results of the pilot. The HHS SNS identifies the anthrax vaccine vials that are nearing expiration and makes those doses available to the participating state and local jurisdictions that request

¹ This wording is extracted from Senate Report 114-251, " First Responder Anthrax Preparedness Act, Report of the Committee on Homeland Security and Governmental Affairs - United States Senate", May 9, 2016.

them through CWMD. The FRVI Pilot participating jurisdictions at the state and local level will provide the education and training for their own emergency response providers (using educational materials provided by CWMD), request the necessary vials of vaccine for their volunteer emergency response providers, administer the required doses per the prescribed sequence, maintain the necessary records to track the progress of individual participants, and assess the potential positive and negative effects of the vaccine program on emergency response missions.

Accomplishments of the FRVI Pilot Program

During the planning for the FRVJ Pilot, HHS ASPR determined there are sufficient anthrax vaccine doses nearing expiration that are available in the SNS to support the FRVI Pilot Program. DHS and HHS established a formal Memorandum of Understanding (MOU) to define roles and missions for the conduct of the FRYJ Pilot and establish mechanisms by which CWMD may request vaccine doses from the SNS for administration to state and local emergency response providers.

HHS ASPR is responsible for stockpiling medical countermeasures for the general public (or first responders). CWMD facilitates the transfer of the vaccine from HHS ASPR to the participating state and local jurisdictions. The MOU also addresses the issue of reimbursement to HHS for the vaccines drawn from the SNS. In accordance with Sec. 2(a)(3)(F) of the Act, the MOU between DHS/CWMD and HHS/ASPR identified the mechanism for the reimbursement of costs and the cost elements that would be included.

CWMD conducted a preliminary analysis of the costs and infrastructure requirements to establish and maintain the FRVJ Pilot. CWMD identified the internal staffing requirements for administration of the FRVI Pilot, developed a scope of work for the proposed Cooperative Agreement (grant) awards, and worked with HHS ASPR to identify the costs involved with shipping vaccine doses from the SNS to the participants.

Under the auspices of the FRVJ Pilot, CWMD conducted a competitive award of Cooperative Agreements (grants) to state and local jurisdictions desiring to participate in the FRYI Pilot. The period of performance for the Cooperative Agreements is two years. The evaluation criteria for the awards included the viability of the applicant ' s technical and operational approach, anticipated operational impact, and management plan. Although not a condition of eligibility, applicants were also encouraged to partner with a university or industry partner with existing capabilities to support one or more goals of the FRVJ Pilot. The Notice of Funding Opportunity was published on the Grants.gov website, and any interested state, regional, or local jurisdictions were invited to download and prepare an application packet. Cooperative Agreements were determined to be the appropriate funding vehicle because grants are legal instruments used by DHS to transfer money or anything of value to an eligible recipient to accomplish a public purpose of support as authorized by federal statute. The entire process was overseen by the DHS Grants and Financial Assistance Division and Financial Assistance Policy Office.

After a review by an objective review panel of all the applications received, two awards were made on September 20, 2019 to the City of St. Louis, Missouri, and the State of Mississippi.

DHS provided funding for the Cooperative Agreements to the two sites in two increments (in September 2019 and in August 2020). The first increment covered the first-year costs with some additional reserve and the second increment provided the remaining balance of the budget justification amounts provided by each awardee in their applications. Under the terms of these Cooperative Agreements, each participating jurisdiction is tasked to identify the high-risk emergency response providers in their respective jurisdictions who might benefit from participation in the FRVI Pilot, administer the CWMD-developed FRVI Pilot training package to the selected emergency response agencies, identify the volunteers in their jurisdictions willing to participate in the program, administer the vaccine doses according to the regimen prescribed by the CDC and using anthrax vaccine doses provided by the SNS, track the continued participation of the volunteers, assess the benefits to their emergency response providers from receiving the vaccine, and report their progress regularly to CWMD.

As part of the FRVI Pilot, CWMD worked with HHS ASPR, CDC, and FDA to develop an interactive PowerPoint training and education package that provides potential state and local volunteers with current information regarding the anthrax threat, the structure of the FRVI anthrax vaccine program, and the potential benefits and side effects of the anthrax vaccine. This PowerPoint presentation was distributed to both participating pilot jurisdictions, where it was administered to emergency response providers through educational visits to selected emergency response agencies (including fire departments, law enforcement agencies, and emergency medical treatment facilities).

In collaboration with the HHS ASPR SNS staff, CWMD established a logistical platform for the anthrax vaccine request process under the pilot program. This system facilitates ordering and tracking of anthrax vaccine doses required by participating state and local jurisdictions while maintaining accountability of doses required by the SNS. Software was developed in-house by CWMD and provides a structured business process, standardized order forms, and a means to track doses that are distributed to participating sites. Using this logistical platform, the average time for a local jurisdiction to receive vaccine doses after placing an order was 4.3 days. This included the 24-hour shipping time from SNS to the site. Of the requested batches of doses, 100 percent were filled by SNS with the precise number of doses requested.

CWMD also established a robust communication platform supporting the FRVI Pilot. This platform resides on the Max.gov website established and maintained by the Office of Management and Budget (OMB) and provides a secure web page accessible to the federal, state, and local FRVI Pilot participants. Once participants register on the site, the web page enables collaboration and distribution of current training materials. In addition, CWMD established a dedicated FRVI email address for ease of access to the CWMD FRYI staff. CWMD also hosts a regular FRYI conference call involving program management and technical experts from CWMD, DHS Science and Technology's Compliance Assurance Program Office (CAPO), HHS ASPR/SNS, CDC, FDA, and the two participating state and local sites. This call enables frequent exchange of ideas and best practices; questions on a variety of topics including regulatory requirements, risks, and best practices; and an opportunity to address any problems encountered by the sites as they execute the pilot.

Throughout the conduct of the FRVI Pilot, both participating sites (the City of St. Louis partnered with Washington University of St. Louis and the State of Mississippi partnered with the University of Mississippi Medical Center) have conducted surveys among the potential volunteer emergency response provider participants. The survey questions were reviewed by Institutional Review Boards (IRBs) and by the DHS CAPO to determine whether the various aspects of the project constituted research involving human subjects and to ensure compliance with the Common Rule 6 CFR part 46, Subpart A, the federal regulation for the protection of human subjects in research. Surveys were administered voluntarily and anonymously and were used to gauge emergency response provider community awareness of the anthrax threat, the structure of the anthrax vaccine program, and potential side effects. The two participating sites maintained and reported statistics of the numbers of volunteers and tracked the progress of those volunteers through the prescribed sequence of vaccine doses. That sequence includes an initial dose, followed by subsequent doses 30 days after the initial dose and again at 6, 12, and 18 months after the initial dose. The CDC recommends a booster dose every 3 years following administration of the full five-shot vaccine series (see <https://www.cdc.gov/mmwr/volumes/68hi/rr6804a1.htm>). However, the long-term administration of boosters is not a part of the FRVI Pilot. That will be a topic for consideration in a potential follow-on national program. The state and local participants report progress monthly to the CWMD Office. Participation in the FRVI program is entirely voluntary. As of September 30, 2020, the FRVI Pilot has provided educational visits to over 55 emergency response agencies, trained more than 1,928 individual emergency response providers, and administered more than 2,307 doses of the anthrax vaccine to individual state and local emergency response volunteers (see section III below for additional details).

Challenges

During the establishment of the FRVI Pilot Program in both participating jurisdictions, there was a requirement in accordance with the Common Rule to obtain the approval from the local IRB prior to initiation of activities to ensure that appropriate steps were taken to protect the rights and welfare of humans participating as subjects in research. Eventually, both the St. Louis and Mississippi IRBs approved the FRVI Pilot programs and the surveys and information collection mechanisms proposed by both jurisdictions. The IRB review process meant a delay of a few weeks in the kickoff of the FRVI programs in both jurisdictions. IRB review and approval may be an issue in an ongoing national program, however, since the data collection process related to standard of care is not considered research, but future efforts related to analysis of this data may be considered research.

During administration of the CWMD FRVI Pilot educational package to fire departments in St. Louis, representatives of the International Association of Fire Fighters (IAFF), a national union representing professional firefighters, raised concerns about the Pilot Program. IAFF representatives recommended their members *not* to volunteer to receive the anthrax vaccine because the FRVI Pilot did not account for loss of pay or overtime compensation for those individuals taking the training and receiving the vaccine. The local FRVI Pilot leads continue to work with the local union representatives to resolve their concerns. Training is usually

scheduled during normal duty hours and shift changes (minimizing the need for overtime), and initial data suggest that vaccination procedures cause minimal loss of work time for participating volunteers (see table on Adverse Events on page 9).

In early February 2020, approximately 4 months after the award of the two FRVI Pilot Cooperative Agreements (and after the educational visits and vaccination programs were underway across the participating sites), the COVID-19 pandemic appeared in the United States. Because many of the individuals involved in the administration of the FRVI Pilot have distinct public health responsibilities in addition to their FRVI Pilot duties, a number of the key personnel were diverted to higher priority tasks in response to the COVID-19 crisis. In addition, at least one of the participating sites (Mississippi) experienced staffing cuts and layoffs because of budget reprioritizations within the state resulting from COVID-19 response requirements. This caused a slower than anticipated outreach to additional emergency response agencies across the jurisdictions. The FRVI Pilot educational visits resumed in both locations in July 2020 as the COVID-19 response activities leveled off; in some cases, however, the participants operated with smaller support staffs than prior to COVID-19. Consequently, the overall effect of the COVID-19 pandemic response on the FRVI Pilot is fewer agencies reached by the participating jurisdictions with the educational package and the initial vaccination doses. CWMD does not anticipate this will dramatically affect our ability to assess the possibility of a follow-on national-level program.

III. Results and Data Report

The FRVI Pilot is currently midway through the 2-year period of performance for the Cooperative Agreements awarded to the participating state and local jurisdictions (the City of St. Louis and the State of Mississippi). Both Cooperative Agreements are fully funded, and all funding was released to grant recipients.

Tabulation of Costs to Administer the Program

Cooperative Agreements awarded to the City of St. Louis and the State of Mississippi have a total funded value of \$980,759 as shown in the following table. These costs were as proposed by the jurisdictions during the competitive award process for the Cooperative Agreements. Dollar values include all costs associated with administration of the FRVI Pilot at the state and local level, including staff labor, infrastructure improvements required for the storage and distribution of the vaccine (which requires constant refrigeration until administered), and local logistics costs associated with the educational visits and vaccine administration at the individual emergency response agency sites.

Cost to Administer the Program

FRVI Pilot Grantee	Total Grant Award	Increment 1 (FY19)	Increment 2 (FY20)
City of St. Louis	\$612,728.00	\$369,167.30	\$243,560.70
State of Mississippi	\$368,031.00	\$322,558.00	\$45,473.00
TOTAL	\$980,759.00	\$691,725.30	\$289,033.70

The following data reflect administrative and management costs at the federal level. Costs include shipment and transportation of vaccines, staff time directly supporting such shipments, the amount (if any) by which warehousing costs of the SNS are increased because of the operation of the pilot, the total costs for management and administration of the pilot, and the total number of full-time equivalents (FTEs) allocated to the program.

The following table summarizes cost elements during execution of the FRVI Pilot through September 30, 2020. The figures represent the total costs to date accrued by OHS and HHS in each category.

Cost Element	DHSCWMD	HHS SNS	Total
Management and administration costs	\$0	\$697	\$697
Vaccine shipment and transportation	\$0	\$427	\$427
Number of FTEs allocated to the program	Less than 0.1	Less than 0.1	Less than 0.1
Cost of the anthrax vaccine	<i>N/A</i>	\$11 8 ,664	\$118 ,664
Total cost	<i>N/A</i>	\$11 9,788*	\$119,788

* The total cost to **HHS SNS** includes the purchase cost of the vaccine doses (not a reimbursable expense under the Act).

Number of Eligible Emergency Response Providers and Statistics

The following table summarizes the extent of participation in the FRVI Pilot by state and local emergency response providers. The participating jurisdictions collected and reported these data to CWMD as of September 30, 2020.

		City of St. Louis	State of Mississippi	Total
Emergency Response Agencies Trained	Emergency Management	1	-	1
	Fire/EMS	25	4	29
	Law Enforcement	17	1	18
	Medical Emergency Department	6	1	7
	TOTAL	49	6	55
Total Eligible Emergency Response Providers	Emergency Management	30	10	40
	Fire/EMS	2,326	765	3,091
	Law Enforcement	3,220	2,151	5,371
	Medical Emergency Department	1,832	207	2,039
	TOTAL	7,408	3,133	10,541
Emergency Response Providers Trained	Emergency Management	30	-	30
	Fire/EMS	726	334	1,060
	Law Enforcement	473	8	481
	Medical Emergency Department	334	23	357
	TOTAL	1,563	365	1,928
	Percent of Eligible Emergency Response Providers Trained	21.1%	11.7%	18.3%
Emergency Response Providers Volunteering for Vaccination Sequence	Emergency Management	21	-	21
	Fire/EMS	437	43	480
	Law Enforcement	271	1	272
	Medical Emergency Department	314	11	325
	TOTAL	1,043	55	1,098
	Percent of Eligible Emergency Response Providers Volunteering	14.1%	1.7%	10.4%

The following table shows the current retention rates of volunteers in the program.

	City of St. Louis	State of Mississippi	Total
Total Emergency Response Providers Trained	1,563	365	1,928
Percentage of Trained Individuals Who Volunteered to Receive the First Dose	66.7%	14.8%	57.0%
Percentage of Volunteers Who Remain after the First Dose	94.6%	96.2%	94.7%

Total Vaccine Doses Administered

The following table summarizes the number of anthrax vaccine doses administered by the sites participating in the FRVI Pilot.

		City of St. Louis	State of Mississippi	Total
<i>Total Vials Requested</i>	From SNS Stocks	300	70	370
Total Doses Administered	Initial	1,000	53	1,053
	30 day	802	51	853
	6 month	382	0	382
	12 month	4	0	4
	18 month	0	0	0
	Booster	15	0	15
	TOTAL	2,203	104	2,307

- This number is less than the total number of volunteers because some had already received at least one dose of vaccine previously while in the military and picked up where they had left off in the sequence.
- While not formally part of the FRVJ Pilot, these boosters were administered to individuals who had completed the full sequence of five doses while in the military.

Of the 1,098 individual emergency response providers volunteering for the vaccination sequence, 75 (6.8%) reported any adverse events. Of these, five (0.46%) missed any work, and two (0.18%) experienced an event that made them unable to perform their normal duties. Of the reported adverse events, 95.2 percent required no treatment of any kind, and 4.8 percent reported a self-prescribed treatment (all over-the-counter ibuprofen or acetaminophen). None required a visit to a healthcare provider. The following table provides some of the initial findings for potential adverse effects of administration of the vaccine sequence to emergency response providers.

	City of St. Louis	State of Mississippi	Total
Individual participants reporting adverse event	75	0	75
Percentage of Total Participants	7.2%	0.0%	6.8%
Graded Mild	87	0	87
Graded Moderate	18	0	18
Graded Severe	0	0	0
Total Adverse Events*	105	0	105

	City of St. Louis	State of Mississippi	Total
Events associated with missed work	5	0	5
Events associated with decreased productivity	44	0	44
Events in which individual could not perform normal duties	2	0	2

- Individual participants can report more than one adverse event (due to receiving multiple vaccinations).

For the final year of the FRVI Pilot, the two sites continue to provide educational visits to additional emergency response agencies, solicit volunteers for the vaccine program, and administer doses in accordance with the prescribed dose sequence. CWMD will assess the overall impact of the COVID-19 pandemic on the administration of the FRVI Pilot program, as well as any perceived synergies between the FRVI Pilot and its affiliated infrastructure and the emerging COVID-19 vaccine program. At the end of the period of performance, the two performers will provide a final summary of the data and any practical recommendations to improve and retain the number of volunteers for the vaccine program.

IV. Analysis/Discussion

CWMD continues to collect data from the two pilot sites. Based on the number of agencies and emergency response providers reached so far, and in light of the restrictions and conflicting priorities brought on by the COVID-19 pandemic, the FRVI Pilot has proven effective in increasing emergency response provider community awareness of the anthrax threat, the efficacy of available anthrax vaccine, and the low incidence of adverse effects for those volunteering to undergo the vaccine sequence.

General Observations

With only two sites participating in the FRVI Pilot, and with delays due to COVID-19 response actions diverting some medical personnel, it is difficult to gather meaningful insights into the potential for a broader nationwide vaccine program. However, certain trends are emerging that provide some useful indications.

The pace of the program (the number of educational site visits and the numbers of individuals trained during the visits) was adversely affected by the pandemic in the spring of 2020. The primary effects occurred because of two factors:

- Public health and emergency medical personnel identified as key performers for the FRVI Pilot were diverted to pandemic response actions.
- COVID-19 restrictions on gatherings of individuals limited the number of people who could be trained at one time and, in some cases, caused emergency response agencies to postpone or cancel FRVI educational visits.

In addition to the pandemic, both St. Louis and several urban areas in Mississippi experienced periods of civil unrest during the first year of the FRVI Pilot Program. These events diverted law enforcement agencies from full participation in FRVI Pilot educational sessions, thereby adversely impacting the number of emergency response providers trained and serving as volunteers in the vaccine program.

In Mississippi, steps were taken under the FRVI Pilot to certify paramedics to administer preventive vaccinations. Previously, they were not allowed to do so. Now, additional medical personnel authorized to administer vaccines are available, particularly in remote rural areas.

Recommendations to Improve Participation in the Pilot Program

Based on the observations in St. Louis and Mississippi, CWMD has identified recommendations for improving initial rates of volunteer participation in the anthrax vaccination program established by the FRVI Pilot, and for improving the retention rate for volunteers already in the program. These recommendations include the following:

- Work with the agencies to fit within their schedule so training and vaccination administration is not disruptive. This is especially important for law enforcement and medical facility emergency departments that tend to have less set education time when everyone is present. This implies conducting education sessions at change of shift or multiple education sessions in a row to capture a small group of emergency personnel at each session.
- Tailor the education to the group that is being approached. Tailor the language to describe the same concepts when talking to police versus paramedics versus physicians. Try to make sure it fits how they might be exposed based on what they do (type of provider, where they work, etc.).
- Have a physician or someone well versed in vaccines in general, side effects, and interactions with medical problems or home medications at education sessions, since

there are a lot of questions about personnel health issues, side-effect risk, or what the data suggest would be the outcome of exposure in different attack scenarios.

- Generate strong buy-in from the agency management, medical directors, or union representatives to encourage emergency personnel to participate and ensure no pressure to volunteer is being put on the individual emergency response providers by their supervisors. It's best if management can be present at the first education/ vaccination session, but even if they are not, the messaging they send to their staff affects uptake. When management stresses the importance of the education and the opportunity to get the anthrax vaccine voluntarily, higher rates of participation and more engagement with the education have been noticed, compared to cases in which the agency chief or medical director do not come at all.

In moving from a pilot project to a national program, best practices and key partners might make a program more successful, or even just viable. Some of these best practices might include:

- State registries for first responders that capture required or administered vaccines would allow programs to monitor the vaccination status of their workforce. These should be linkable to individual health records through secure, private mechanisms.
- Leverage in-place infrastructure, such as chain pharmacies, to administer the vaccine to local first responders on a reimbursable basis. The SNS stores the 10-dose vials in large crates that must be broken down to smaller bundles. The chains could order directly from the SNS in larger bulk, then distribute through their own supply/ logistics processes to be administered locally by the pharmacist, with the administration being documented in the state's First Responder Vaccine Registry. The vaccine booster could be given in conjunction with other vaccines, such as annual flu, much more conveniently. Systems might also allow batch ordering of anthrax from the SNS (e.g., must have a group of 6-10 first responders within the open vial expiration date at a location to avoid wastage). A vaccine app could identify the group, schedule the visit, and coordinate groups large enough to cover the 10-dose vial in a given location. It would be interesting to try to leverage this at a FRVI Pilot site as a proof of concept.
- Pool vaccination data and side-effect profiles at the national level. This would provide a better understanding of the risk of time lost or impact to work for the vaccine and inform more effective vaccination dosing to minimize effects or lost work since adverse events are rare from vaccines.

Here are some additional lessons learned regarding administration of the program from a rural perspective:

- Engagement with local primary care physicians is an important part of obtaining first-responder buy-in for the anthrax vaccination program. The need for local physicians to "bless" the program and confirm vaccine safety was highlighted by how often first responders asked if local physicians endorsed the program and how a lack of this endorsement served as a barrier to vaccination.
- Shipment of vaccines to an academic medical center was different from the usual pharmacy process, creating some challenges in notification of refrigerated items through nonpharmacy protocols. A suggestion for a more widespread anthrax vaccination program would be to follow normal medical supply chain processes.

- Entering vaccinations into the electronic medical record (EMR) is a necessary aspect of healthcare documentation. In Mississippi, the EMR system was able to be easily adapted to record the anthrax vaccination. However, if the vaccination program is adopted throughout the Nation, it would be worthwhile briefing the first-responder anthrax vaccination program to the dozen or so major EMR manufacturers so they can adapt their EMR products to the needed additions of vaccines and countermeasures.
- Develop a process for risk stratification among first responders and healthcare workers. In Mississippi, they used a "most likely" approach to target certain providers, such as hazardous materials teams, special operations teams, and emergency department workers in larger cities as part of their selection criteria for potential volunteers. Mississippi program leaders noted there was limited guidance from the Federal Government in identifying "higher risk" emergency response providers.
- Anthrax vaccine electronic information should include Frequently Asked Questions (FAQs) and responses. This electronic information should be available before the in-person education activities.
- In Mississippi, it was difficult to communicate with rural first responders. Many departments communicate via phone and fax without the ability to disseminate or receive mass notifications. Apparently, fire personnel, law enforcement officers, emergency management agencies, and emergency medical services do not have a consistent way of communicating and pushing information to various first-responder disciplines throughout the state.

V. Conclusion/DRS Action Plan

The FRVI Pilot is demonstrating that state and local emergency response providers are willing to volunteer for an anthrax vaccination program, provided they are properly trained and educated on the reality of the anthrax threat, the structure of the vaccine countermeasure available to them, and the potential for adverse effects from receiving the vaccine sequence. Current data indicate a low occurrence of adverse events.

DHS and HHS will continue the FRVI Pilot Program through the end of fiscal year 2021, at which time they will consolidate all the data collected into a final report as required by Section 2(a)(8)(B) of the Act that will: (1) consider whether the FRVI Pilot Program should continue after December 2021 (and in what form); (2) include a cost-benefit analysis and an explanation of the economic, health, and other risks and benefits of administering vaccines through the pilot rather than post-event treatment; and (3) if it is recommended that the pilot program continue, a plan under which it could be continued.

Over the next year, both St. Louis and Mississippi will continue to expand coverage of emergency response agencies, delivering the anthrax vaccine educational package to a wider audience of emergency response providers, soliciting additional volunteers for the vaccine program, and collecting data on the positive benefits of the program, as well as any adverse events resulting from the vaccinations. Both sites will continue to refine their recommendations for increasing the participation in the voluntary program among the eligible emergency response providers in their respective jurisdictions.

CWMD will continue to receive and process requests for anthrax vaccine doses from both participating sites in accordance with the FRVI Pilot business process model currently in effect. HHS SNS will continue to draw requested vaccine doses from the SNS warehouse and ship the requested vials to the pilot sites. Both CWMD and SNS will continue to monitor the costs incurred in the administration of the pilot and will collaboratively determine a recommendation for the advisability of continuing the FRVI beyond the December 2021 end date of the pilot.

Appendices

A. Certifications

B. List of Acronyms and Abbreviations

CERTIFICATIONS

The Department of Homeland Security reports that both participating jurisdictions (the City of St. Louis and the State of Mississippi) have provided written certification to DHS that each emergency response provider within the state that participates in the pilot program is provided with disclosures and educational materials designated by the Secretary of the Department of Health and Human Services, which may include-

- (A) materials regarding the associated benefits and risks of any vaccine provided under the pilot program, and of exposure to anthrax;
- (B) additional material consistent with the Centers for Disease Control and Prevention's clinical guidance; and
- (C) notice that the Federal Government is not obligated to continue providing anthrax vaccine after the date on which the pilot program ends.

Appendix B: List of Acronyms and Abbreviations

ACRONYMS AND ABBREVIATIONS

ASPR	Assistant Secretary for Preparedness and Response
AVA	Anthrax Vaccine Adsorbed
CAPO	DHS Compliance Assurance Program Office
CBRN	Chemical Biological Radiological and Nuclear
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease
CWMD	Countering Weapons of Mass Destruction
DHS	Department of Homeland Security
FDA	Food and Drug Administration
FRVI	First Responder Vaccine Initiative
HHS	Department of Health and Human Services
IAFF	International Association of Fire Fighters
IRB	Institutional Review Board
MOU	Memorandum of Understanding
POC	Point of Contact
SNS	Strategic National Stockpile