DHS First Responder Vaccine Initiative Pilot Program

May 9, 2022

Second Annual Report to Congress

Homeland Security

Countering Weapons of Mass Destruction Office

Message from the Acting Assistant Secretary for Countering Weapons of Mass Destruction

The following annual report, *DHS First Responder Vaccine In*itiative (FRVI) Pilot Program, was 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 and Commerce

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

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

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

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

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

Sincerely,

Gary Rasicot
Acting Assistant Secretary

Executive Summary

The Second Annual 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 (HHS), 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 specific elements on the progress and results of the pilot program prescribed in Section 2(a)(8)(A) of the Act. A Final Report will follow in accordance with Section 2(a)(8)(B).

The Department of Homeland Security (DHS) Countering Weapons of Mass Destruction Office (CWMD), working in conjunction with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), executed the First Responder Vaccine Initiative Pilot that made anthrax vaccine doses nearing their expiration available on a voluntary basis to state and local emergency response providers for pre-exposure prophylaxis (PrEP) vaccination. DHS 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 informed potential volunteer vaccine recipients from the emergency response provider community about the anthrax threat, the nature of the vaccine program as a preventive medical 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 to conduct a pilot in their respective jurisdictions, incrementally funded in Fiscal Year (FY) 2019 and FY 2020. As of September 30, 2021, a total of 2,738 emergency response providers from 66 emergency response agencies were educated under the FRVI Pilot Program, and 1,253 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).

Although current events had a direct impact on the FRVI Pilot sites, CWMD does not anticipate this will affect our ability to assess the possibility of a broader follow-on program in the final report. The FRVI Pilot outreach to emergency response agencies 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. Many target agencies were also extremely challenged by the pandemic response and, for the case of law enforcement, preparation for potential incidents of social unrest. Vaccinations against COVID-19 caused further delays as first responders stood by for their opportunity to receive the COVID-19 vaccine. The overall effect of these delays was fewer agencies reached by the participating jurisdictions with the educational package and the initial anthrax vaccination doses.

As of September 30, 2021, a total of 583 vials (5,830 doses) of the anthrax vaccine were released from the HHS ASPR-managed Strategic National Stockpile for administration to volunteers and of these, 3,680 doses were administered under this pilot in accordance with the following breakdown by dose in the vaccination series.

Total Doses Administered as of 30 Sep 2021	Initial	1,194
	30 day	1,053
	6-month	805
	12-month	490
	18-month	119
	Booster*	19

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

DHS, HHS, and the two FRVI Pilot sites continued the FRVI Pilot Program through December 14, 2021, when the pilot mandate expired. DHS will assess overall costs and perceived benefits and prepare a recommendation for the advisability of any follow-on first-responder vaccine program in a final report to Congress.

DHS First Responder Vaccine Initiative Pilot Program Second Annual Report to Congress

Table of Contents

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 (DHS) Countering Weapons of Mass Destruction Office (CWMD), DHS executed a First Responder Vaccine Initiative (FRVI) Pilot that had 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 jurisdictions (as required by their Cooperative Agreement award). Following this pilot program, DHS will develop recommendations regarding the advisability of a follow-on program. This is being accomplished in operational partnership and through coordination with the Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR), Division of the Strategic National Stockpile (SNS).

Purpose

The purpose of the FRVI Pilot was to carry out a pilot program to provide eligible anthrax vaccines from the SNS to selected state and local emergency response providers and 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 was not open-ended. In other words, it did not implement long term sustainment of a First Responder Vaccine Program, but rather identified applicable procedures and likely costs for such a notional future program. It was intended to identify meaningful recommendations for consideration in continuing a vaccination program beyond the expiration date of the Pilot. To be clear, it was not charged specifically with looking at how the Pilot would scale into a national level program, but the Pilot partners are interested in exploring factors required to implement a broader program.

The FRVI Pilot solicited volunteer emergency response providers from state and local agencies that have a role in responding to a potential anthrax attack or incident, drew necessary vaccine doses from the SNS, and administered 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.[2] 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 oversaw the conduct of the pilot, provided necessary resources to state and local jurisdictions through competitive Cooperative Agreements, and will assess the results of the pilot. The HHS SNS identified the anthrax vaccine vials nearing expiration and made those doses available to participating state and local jurisdictions that requested them through CWMD. The FRVI Pilot participating jurisdictions at the state and local level.

---

[1] U.S. Senate. Committee on Homeland Security and Governmental Affairs. *First Responder Anthrax Preparedness Act*, (to accompany S.1915) (S.Rpt.114-251). May 9, 2016.

[2] Bower WA, Schiffer J, Atmar RL, et al. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices, 2019. https://www.cdc.gov/mmwr/volumes/68/rr/rr6804a1.htm.;

- provided the education and training for their own emergency response providers (using educational materials provided by CWMD),
- requested the necessary vials of vaccine for their volunteer emergency response providers,
- administered the required doses per the prescribed sequence,
- maintained the necessary records to track the progress of individual participants, and
- assessed 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 FRVI Pilot, HHS ASPR determined there were sufficient anthrax vaccine doses nearing expiration that were 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 FRVI 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 facilitated transfers of the vaccine from HHS ASPR to participating state and local jurisdictions. The MOU also addressed the issue of reimbursement to HHS for 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 reimbursement of costs and cost elements for inclusion.

CWMD conducted a preliminary analysis of cost and infrastructure requirements to establish and maintain the FRVI Pilot. CWMD identified 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 costs involved with shipping vaccine doses from the SNS to the participants.

Under the auspices of the FRVI Pilot, CWMD conducted a competitive award of Cooperative Agreements (grants) to state and local jurisdictions desiring to participate in the FRVI Pilot. The period of performance for the Cooperative Agreements was two years, however, each site was approved a no-cost extension to maximize completions of the 18-month dosing sequence amongst volunteers prior to expiration of the Act. Evaluation criteria for the awards included viability of the applicants' 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 FRVI 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 competitive award process was overseen and administered in conjunction with financial guidelines set forth in policies of the DHS Chief Financial Officer's (CFO) Grants and Financial Assistance Division and Financial Assistance Policy Office.

After a review by an objective review panel of all 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 Cooperative Agreements to the two sites in two increments (in September 2019, and in August 2020). The first increment covered first-year costs with some additional reserve and the second increment provided the remaining balance of budget justification amounts provided by each awardee in their applications. Under the terms of these Cooperative Agreements, each participating jurisdiction…

- identified high-risk emergency response providers in their respective jurisdictions,
- administered the training package to selected emergency response agencies,
- identified volunteers in their jurisdictions,
- administered the vaccine doses provided by the SNS,
- assessed benefits to their emergency response providers receiving the vaccine, and
- reported their progress regularly to CWMD.

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

In collaboration with 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 from the SNS. Software was developed in-house by CWMD and provides a structured business process, standardized order forms, and a means to track doses distributed to participating sites. Using this logistical platform, the average time for a local jurisdiction to receive vaccine doses after placing an order was 2.5 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.

The communication platform established by CWMD for supporting the FRVI Pilot remained accessible during the second year of the pilot program execution to FRVI partners. 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 continued to utilize a dedicated FRVI email address for ease of access to the CWMD FRVI staff. CWMD also continued to host a regular FRVI conference call involving program management and technical experts from CWMD, DHS Compliance Assurance Program Office (CAPO), HHS ASPR/SNS, CDC, FDA, and the two participating state and local sites. This call enabled

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 sites as they executed the pilot.

Throughout the FRVI Pilot, both participating sites[3] conducted surveys among the potential volunteer emergency response provider participants to support the evaluation of the pilot's efficacy. The survey questions were reviewed by Institutional Review Boards (IRBs) and by the DHS CAPO which determined the various aspects of the project did not constitute research involving human subjects and ensured compliance with Common Rule 6[4], 6 CFR part 46, Subpart A, the federal regulation for the protection of human subjects in research. During the second year of the pilot's execution, surveys were administered voluntarily and anonymously, as in the first year, 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. The CDC recommends a booster dose every three (3) years following administration of the full five-shot vaccine series (see https://www.cdc.gov/mmwr/volumes/68/rr/rr6804a1.htm). However, the long-term administration of boosters is not a part of the FRVI Pilot. This is a topic for consideration in a potential follow-on program.

State and local participants reported progress monthly to the CWMD Office. Participation in the FRVI program was entirely voluntary. From September 29, 2019, until September 30, 2021, the FRVI Pilot provided educational visits to 66 emergency response agencies, trained 2,738 individual emergency response providers, and administered 3,680 doses of the anthrax vaccine to individual state and local emergency response volunteers (see section III below for additional details).

Challenges

The COVID-19 pandemic continued to hinder the outreach efforts of both participating pilot sites to emergency response agencies. The phased COVID-19 vaccination campaign hindered participation in the pilot, as the first responder communities stood by in anticipation of becoming eligible for the COVID-19 vaccine while observing CDC's original guidance to not receive the COVID-19 vaccine within two weeks of any other vaccinations. Furthermore, many public health administrators working on the FRVI Pilot were diverted to higher priority response duties in their local jurisdictions throughout the pandemic, which resulted in personnel shortages. As an example, Mississippi personnel responsible for the FRVI Pilot were also responsible for creating and staffing two new field hospitals and a field infusion clinic on the campus of the University of Mississippi Medical Center, while others were re-assigned to emergency and hospital COVID-19 related duties across the state. The situation was further compounded by emergency response agencies and local public health departments themselves being overwhelmed by continuous preparations and trainings as COVID-19 guidelines evolved. Some agencies implemented periods when they did not allow any new FRVI educational, or catch-up

[3] 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

[4] 45 C.F.R. Part 46, Subpart A

vaccination visits and others were made inaccessible by mandated travel and meeting restrictions. Consequently, the overall effect of the COVID-19 pandemic response on the FRVI Pilot was fewer agencies reached by participating jurisdictions with the educational package and initial vaccination doses. CWMD does not anticipate this will dramatically affect our ability to assess the possibility of a follow-on program.

Misinformation surrounding the release of newly developed COVID-19 vaccines and the COVID-19 pandemic fostered vaccine hesitancy and mistrust, which challenged voluntary participation among first responder groups in both St. Louis and Mississippi. Although experienced by both sites, Mississippi seemed especially affected. In some cases, this was partially overcome by having a physician attend the education sessions to provide straightforward explanations about the anthrax vaccine and answer questions including individual medical questions from first responders. However, the information and misinformation regarding COVID-19 seemed to consume the interest and concern of the pilot's specific population, thereby reducing the number of volunteers opting to participate in this pilot.

Meeting the requirements of the various agencies and personnel changeover imposed further setbacks in expanding the population of vaccinated first responders. As reported in the First Annual Report, initial delays were experienced by both St. Louis and Mississippi as they both sought Institutional Review Board (IRB) approvals of their proposed programs, surveys, and information collection mechanisms in their respective jurisdictions. Subsequent delays occurred throughout the pilot due to some agencies requiring their administration (i.e., medical directors, human resources, risk management, etc.) to first review the pilot program before scheduling the initial education session. The challenge of coordinating volunteers' individual availability to coincide with the FDA-approved and CDC-recommended PrEP dosing schedule also slowed the pilot's progress. Amidst these delays, changeovers in both leadership and key personnel at the federal, state, local, and agency levels further complicated pilot operations as new staff and stakeholders had to be brought up to speed.

Due to the Cooperative Agreements being awarded in September of 2019, both sites were challenged to administer the 18-month vaccine regimen within their two-year periods of performance. With minimal buffer time, any setbacks in engaging with the eligible emergency responders resulted in decreased participation. Participating jurisdictions effectively had six months following notification of grant approval to initiate the pilot and administer initial vaccine doses to volunteers with ample time to complete the 18-month series under the pilot. All volunteers were informed of the possibility of not completing the 5-dose series through the pilot and, if they so choose, they can receive any remaining doses at their own expense with a valid prescription from a travel clinic. Both sites were awarded no-cost extensions to use remaining funds for maintaining First Responder anthrax vaccine status. Mississippi's grant was extended until October 31, 2021, while St. Louis' grant was extended beyond the period of the pilot until September 30, 2022.

III. Results and Data Report

The FRVI Pilot's participating state and local jurisdictions (the City of St. Louis and the State of Mississippi) completed the second consecutive year of pilot execution. Both Cooperative Agreements were fully funded, and all funding was released to grant recipients. Tables shown in this section document the FRVI Pilot's cumulative results and data, including both the first and second year of execution through September 30, 2021.

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.

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 of the FRVI Pilot through September 30, 2021. The figures represent the total costs accrued by DHS and HHS in each category.

Cost Element	**DHS CWMD**	**HHS SNS**	**Total**
Management and administration costs	$537,805.00*	$1,097.00	$538,902.00
Vaccine shipment and transportation	$0.00	$675.00	$675.00
Number of FTEs allocated to the program	0.2	0.1	0.3
Cost of the anthrax vaccine	N/A	$188,784.00	$188,784.00
Total cost	$537,805.00	$190,556.00**	$728,361.00

* Includes planning and initiation costs as well as federal staff time to manage and administer the pilot.

** 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 cumulative participation in the FRVI Pilot for both the first and second year of execution by state and local emergency response providers. Participating jurisdictions collected and reported these data to CWMD as of September 30, 2021.

		City of St. Louis	State of Mississippi	Total
Emergency Response Agencies Trained	Emergency Management	3	–	3
	Fire/EMS	25	7	32
	Law Enforcement	23	1	24
	Medical Emergency Department	6	1	7
	TOTAL	**57**	**9**	**66**
Total Eligible Emergency Response Providers	Emergency Management	120	10	130
	Fire/EMS	2,326	921	3,247
	Law Enforcement	3,220	2,151	5,371
	Medical Emergency Department	1,832	103*	1,935
	TOTAL	**7,498**	**3,185**	**10,683**
Emergency Response Providers Trained	Emergency Management	97	–	97
	Fire/EMS	1,306	334	1,640
	Law Enforcement	625	8	633
	Medical Emergency Department	345	23	368
	TOTAL	**2,373**	**365**	**2,738**
	Percent of Eligible Emergency Response Providers Trained	31.6%	11.5%	25.6%
Emergency Response Providers Volunteering for Vaccination Sequence	Emergency Management	29	–	29
	Fire/EMS	452	42*	494
	Law Enforcement	389	1	390
	Medical Emergency Department	329	11	340
	TOTAL	**1,199**	**54**	**1,253**
	Percent of Eligible Emergency Response Providers Volunteering	16.0%	1.7%	11.7%

* This number was reconciled following the first Annual Report and represents the correct value.

In accordance with Sec.2(a)(8)(A)(ii) of the Act, the previous table reports the percentage of eligible emergency response providers, as determined by each jurisdiction, that volunteer to participate. However, it was not possible for the sites to engage with every eligible emergency response provider identified to establish participation in the pilot program and therefore only those providers that received the education and training were given the opportunity to volunteer.

The following table shows the current volunteer and retention rates of volunteers in the program in year one (Y1) and the total for years one and two (Y1+Y2).

	City of St. Louis (Y1 | Y1+Y2)		State of Mississippi (Y1 | Y1+Y2)		Total (Y1+Y2)
Total Emergency Response Providers Trained	1,563	2,373	365	365	2,738
Percentage of Trained Individuals Who Volunteered to Receive the First Dose	66.7%	50.5%	14.8%	14.8%	45.8%
Percentage of Volunteers Who Remain after the First Dose	94.6%	93.1%	96.2%	37.0%	90.7%

Mississippi did not train additional emergency response providers in the second year of the pilot's execution and therefore its percentage of trained individuals who volunteered did not change from FRVI's previous annual report. On the other hand, St. Louis' volunteer rate has decreased from 66.7 percent after the first year to 50.5 percent after the second. This decrease is a result of introducing virtual and asynchronous training options during the second year of the pilot's execution in response to the in-person training restrictions noted previously. While these new training mediums only showed approximately 24 percent and 1 percent volunteer rates respectively, the in-person education volunteer rate remained consistent with last year's reported rate at about 68 percent.

Although the retention rate reported by St. Louis remained relatively constant across the past two years, Mississippi's rate decreased from 96.2 percent after the first year to 37.0 percent after the second year. This is explained in part by Mississippi only administering the initial and 30-day doses from the complete 18-month series at the time of last year's reporting. Since then, the challenges described previously adversely impacted their percentage of volunteers who remained after the first dose.

Total Vaccine Doses Administered

The following table summarizes the number of anthrax vaccine doses administered by the sites participating in the FRVI Pilot. This table provides the gross number of doses administered in each category. This table should not be used as an indication of the participants' continuation in the dosing regimen, that information can be found in the previous table that reports the percentage of volunteers who remain after the first dose.

		City of St. Louis	State of Mississippi	Total
Total Vials Requested	From SNS Stocks	500	83	583
Total Doses Administered	Initial	1,140*	54	1,194
	30 day	1,004	49**	1,053
	6-month	766	39	805
	12-month	457	33	490
	18-month	119	0	119
	Booster***	18	1	19
	TOTAL	**3,504**	**176**	**3,680**

* 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.

** This number was reconciled following the first Annual Report and represents the correct value.

*** While not formally part of the FRVI Pilot, these boosters were administered to individuals who had completed the full sequence of five doses while in the military.

Of the 1,253 individual emergency response providers volunteering for the vaccination sequence, 99 (7.9 percent) reported any adverse events with the most common side effect being pain at the injection site. Of these, eight (0.64 percent) missed any work, and two (0.16 percent) experienced an event that made them unable to perform their normal duties. Of the reported adverse events, 96.2 percent required no treatment of any kind, and 3.8 percent reported a self-prescribed treatment (all over-the-counter ibuprofen or acetaminophen). None required a visit to a healthcare provider. All adverse events were volunarily reported via St. Louis' post-vaccine follow-up surveys. Although Mississippi solicited its volunteers after their initial dose and each subsequent dose, no side effects were reported. 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	99	0	99
Percentage of Total Participants	8.2%	0.0%	7.9%
Graded Mild	114	0	114
Graded Moderate	19	0	19
Graded Severe	0	0	0
Total Adverse Events*	**133**	**0**	**133**

* Individual participants can report more than one adverse event (due to receiving multiple vaccinations).	City of St. Louis	State of Mississippi	Total*
Events associated with missed work	8	0	8
Events associated with decreased productivity	60	0	60
Events in which individual could not perform normal duties	2	0	2

For the final report, 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

Based on the number of agencies and emergency response providers reached, 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, increasing the efficacy of available anthrax vaccine, and highlighting the low incidence of adverse effects for those volunteering to undergo the vaccine sequence.

General Observations

Despite only two sites participating in the FRVI Pilot and delays caused by COVID-19 response actions, certain trends emerged that provide meaningful insights into the potential for a broader vaccine program, with appropriate staffing and funding for all involved entities.

In assessing COVID-19 vaccination efforts, greater success was achieved by engaging hospitals and public health agencies that had the capacity and experience to administer a large program. The staffing for vaccine clinics was often pulled from existing infrastructure. Similarly, a follow-on FRVI Program could benefit from engaging with groups having experience with outreach in the first responder community, medication/vaccine administration, data tracking, and ample existing infrastructure.

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 and beyond. Primary effects occurred because of three 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 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.
- The climate that dominated the COVID-19 vaccine implementation bled into the

FRVI Pilot Program and made overcoming vaccine hesitancy more difficult. This became another barrier to first responders wanting the Anthrax education and vaccine.

Successful outreach efforts to target agencies and their personnel depended on several factors. Some agencies were interested in the pilot but were unable to engage as they prepared for or responded to higher priorities which made capacity a key factor. Another important factor was establishing multiple points of contact within agencies to increase the likelihood of successfully coordinating engagements. Garnering support from trusted leaders and local institutions such as unions notably improved openness of first responders towards the pilot program. Skepticism of the FRVI Pilot Program was mainly due to participants hearing about the effort from the local program itself.

Recommendations to Improve Participation in the Pilot Program

Based on observations in St. Louis and Mississippi, CWMD 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.).
- Make Anthrax vaccine information (such as Frequently Asked Questions (FAQs) and responses) available electronically before the official education session. This would allow time for interested individuals to digest information, conduct their own research, and prepare questions prior to making their decision whether to volunteer to receive the initial dose.
- 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 personal 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 is 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.

- Enlist the help of local or regional thought leaders in HAZMAT and CWMD such as Civil Support Teams to provide the educational component. Civil Support Team are local, authoritative, already vaccinated, and a trusted source on vaccinating first responders.
- Piggyback onto already scheduled training programs for first responders or incorporate training in new-trainee programs to provide early protection.

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

- Implement state registries for first responders that capture required or administered vaccines and link to individual health records through secure, private mechanisms. State registries would enable monitoring of a workforce's vaccination status.
- Enter vaccinations into the electronic health record (EHR) as a necessary aspect of healthcare documentation. In Mississippi, the EHR system was able to be easily adapted to record the anthrax vaccination. However, if the vaccination program is adopted further, it would be worthwhile briefing the first-responder anthrax vaccination program to the dozen or so major EHR manufacturers so they can adapt their EHR products to the needed additions of vaccines and countermeasures.
- Identify local or regional partners to manage the considerable effort to provide an experienced, orderly, and professional infrastructure of vaccine logistics. These partners must possess the ability to manage [24/7] short-dated material from the SNS that includes but is not limited to efficient ordering, receipt, proper handling, management, tracking, secure storage, and clinical administration of the anthrax vaccine – all the while preserving the cold storage requirements and the privacy of personal health information.
- Use a systematic risk stratification approach to identify the full range of those who would be most susceptible for the crippling effect of an Anthrax attack or who are expected to maintain continuity of operations and government no matter the crisis. Some examples beyond the first responder community include security forces, emergency receivers (in the Emergency Rooms of the large hospital systems), utilities workers, in addition to public works and community services personnel.
- Deploy a unified communication and collaboration platform to serve as a centralized database as well as an outreach and engagement tool for communities determined to be eligible for pre-event vaccination under the scope of a FRVI program.

Additional lessons learned regarding administration of the program:

- 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.

- Communication challenges were present in rural environments. In Mississippi, 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. Many of these communication issues were resolved with weekly telecons and news briefings initiated by Mississippi Center for Emergency Services' Medical Director to first responder leaders across the state.
- Many first responders knew nothing about anthrax or that an anthrax vaccine existed prior to this pilot which led to some skepticism about whether the information was true and why the program was happening now. Conversely, COVID-19 vaccination benefited from having a large amount of education about the disease and the vaccine available through the media and the internet, which led many to desire to be vaccinated before they were offered the opportunity. Future FRVI programs would benefit from a coordinated outreach to the first responder community to raise awareness about anthrax risk and the vaccine as a means of protection.

V. Conclusion/DHS Action Plan

The FRVI Pilot demonstrated 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 and no occurrences of serious adverse events.

Similar to most steady-state public health activities, the FRVI Pilot Program was undoubtedly affected by the COVID-19 pandemic. At the partner site level, dedicated program staff were repurposed to focus mostly on pandemic response, limiting the availability to increase awareness of the pilot program and reinforce engagement with partners. Although it was not explicitly documented that subject attrition in the program was a result of COVID-19 vaccine mandates, vaccine hesitancy, the overall impact of the uncertainty of the pandemic, and several program changes resulting from the pandemic, these factors may have altered outcomes.

Both partner site locations experienced substantial declines in volunteers and established participants concurrent to the pandemic. Despite modifications in training to meet state and local mandates, participation was significantly lower and often times follow-up questions were related to COVID-19, not anthrax. The results of the second year of the pilot program should be considered in context of the pandemic, especially related to the overall outcome. The impacts of the pandemic will be reported in more detail within the final report. Despite difficulties brought on by COVID-19, enough valid data was collected during the pilot program to support a recommendation regarding the advisability of any follow-on first-responder vaccine program.

DHS and HHS continued the FRVI Pilot Program until the expiration of the First Responder Preparedness Act on December 14, 2021. A consolidated report of all the data collected will be incorporated 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.

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.

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
CFO	Chief Financial Officer
COVID-19	Coronavirus Disease
CWMD	Countering Weapons of Mass Destruction
DHS	Department of Homeland Security
EHR	Electronic Health Record
FDA	Food and Drug Administration
FRVI	First Responder Vaccine Initiative
FTE	Full Time Equivalent
HHS	Department of Health and Human Services
IRB	Institutional Review Board
MOU	Memorandum of Understanding
POC	Point of Contact
PrEP	Pre-Exposure Prophylaxis
SNS	Strategic National Stockpile