Initial Experience With Mass Immunization as a Bioterrorism Countermeasure

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Anthrax vaccine was administered to approximately 5000 individuals at a deployed location near Iraq in a 1-week period. This report describes the planning and administrative process to initiate such a program, with a snapshot view of the first week of immunization. Compliance with this program was important to best protect troops in this high-threat region. The authors share their experience and detail the process of handling refusals, as these are most likely to reveal themselves at the beginning of an immunization program. The program resulted in a compliance rate of 98%. With increased terrorist threats and widespread availability of biologic agents of mass destruction, experiences with such immunization programs should be described in the literature and analyzed in anticipation of similar programs in the future.

With the rise of terrorist activity to include attacks in the United States using anthrax, the planning tempo for immunization of US military troops accelerated during the past year. Once orders were received to implement the program throughout the US Air Force, an anthrax steering group to include top leadership was established at our deployed location. Ownership of the program was given to the unit commanders for administrative actions on refusals and tracking responsibilities. Designated personnel within each unit assured compliance and tracking of individuals, relieving the medical staff of these responsibilities. Shot administration, education, and medical consultation were left to medical personnel.

Cardinal rules of risk communication were considered, and mechanisms were put in place for questions and concerns about getting the vaccine, as well as for handling refusals and misconceptions about the vaccine. Understanding and careful risk communication are especially important in the aftermath of the terrorist attacks of 2001. Approximately 20 hospital staff volunteered to help provide the vaccines, and hospital administration dedicated extra time in meetings and planning—with no impact on the ongoing mission and health care provided with status quo.

A slide presentation was developed by the Public Health Department and presented to the medical group several times with many revisions; the final draft was presented to the commanders. The final draft was then improved several times before being made available on a shared drive on the local area network, allowing for updates whenever the steering group deemed necessary. Detailed notes pages provided background for the slides, with opportunities for commanders to ask questions before they briefed their squadrons. Up-to-date references were included in the briefs to include treatment and Public Health Department concerns. Three basic points were emphasized at the beginning and conclusion of the presentation: (1) The threat is real, especially with the location of the base and the timing with tensions rising with Iraq. (2) Inhalational anthrax kills. (3) The vaccine is safe and protects against anthrax.

Some individuals had concerns, such as whether they would get anthrax from the vaccine and whether those who had previously received part of the six-shot series would have to take all six shots again. Many were relieved to find out they did not have to start the series over and that they could continue where they left off. Some women had questions regarding pregnancy and the vaccine. Medical representatives prepared with references were available to provide answers to questions at the end of presentations. Other online references were handy for medical representatives and the nonmedical deployed US Air Force population.

Metrics developed to demonstrate compliance with the program were divided by units and presented to the leadership. For the purpose of this article, the term compliance is defined as the percentage of individuals who received the shot (including individuals in need of boosters) in the base population. Individuals with administrative and medical exemptions were excluded. Administrative exemptions were mainly based on time in theater, ie, those only there for a few more weeks did not need to start the series.
Perhaps our experience can serve as a baseline metric for future military and civilian programs to determine progress or success. If a population is getting an initial immunization, compliance rate and/or lack of serious adverse effects may be compared to our results and experience. Our findings may be generalized (with limitations) to new vaccination programs in the US civilian population. We believe that compliance is the least generalizable finding, as the military has administrative procedures to maximize participation. The lack of severe reactions can be generalized, taking age and other nonmodifiable modifiers into consideration.

Our process and planning can also be used for initializing a mass immunization program in a defined population. An example may include planning for smallpox vaccination in the military and possibly to the general population in the future. When compared to coalition forces in similar high-risk areas overseas where vaccination was voluntary, our compliance rates were more than triple those of other forces (approximate, based on shared experiences).

Vaccination Process
Schedules were mutually developed with the Public Health Department and the unit designees to fit around busy work schedules and flying missions. The vaccine was administered in three locations. The main location was an expansion tent (a large tent to allow for expanding the capacity of the deployed hospital) near the main hospital. Vaccine was also administered on a smaller scale at two separate acute care clinics on the base. After signing in, a one-page laminated questionnaire was reviewed by potential vaccine recipients (Figure). “Yes” responses were then referred to a provider for review of potential contraindications to the vaccine.

Vaccine recipient data and injection information were entered into laptops on a local area network server and tied into a central database in the United States. The database used was the Air Force Complete Immunization Tracking Application.

Tracking vaccine compliance is valuable and is also done in the civilian sector. The structured query language database was exported to Microsoft Excel and compatible with unit databases for 100% tracking.

The challenge of maintaining temperature of the vaccine was overcome by an organized process in the three centralized locations. Temperature of the vaccine needed to stay between 3 and 10 degrees Celsius. Backup power supplies and alternative refrigeration to maintain the desired temperature range were available at all locations.

Administrative Process
Procedures for dealing with refusals in a timely manner were in place and addressed proactively. The vaccine program was compulsory in that active duty personnel were to be vaccinated unless there were medical contraindications or administrative exceptions. However, contraindications were not limited to pregnancy, eczema, and atopic dermatitis (see Figure).

Individuals who identified themselves as potential refusals were provided the opportunity to consult with a physician about the benefits and risks of the vaccine and/or address concerns about adverse effects. During some of the briefings, individuals spoke up about reports from the BioPort plant closure and confusion regarding Food and Drug Administration approval that was on the Internet. Providers were ready with consistent, sound data to respond to such comments and questions, and when the provider was unsure of the answer, an allergist was available for final consultation. We speculated that if some individuals were allowed to refuse the shot and made it known to peers, the compliance rate would have dropped significantly. This was deduced from conversations among friends of potential refusals on a confined base.

Results
Anthrax immunizations were successfully administered to 98% of the deployed military installation of several thousand people. The remaining 2% was partially due to administrative exceptions (not in theater long enough to be of benefit), medical contraindications, and a few tracking errors. There were no refusals after the first week.

No serious adverse effects occurred, with only the expected minor aches and local reactions manifesting. There were a few vasovagal and arthus reactions, which were expected. Most individuals complained of arm pain; however, because of the proactive education programs and proper dissemination of information to include proper press, this was not a factor in the success of the program.

Influenza vaccine was administered concurrently in the opposite arm to all personnel. There were no apparent cross-reactions between the influenza and the anthrax vaccines in this population during follow-up examinations and discussions with commanders.

No statistical methods were necessary, because we were dealing with the entire population described. There were no needlesticks among the medical staff administering the shots. The 1-week interval for this review was chosen for several reasons, the main one being the high turnover of personnel. For the same reason, only minimal follow-up was possible, with no long-term follow-up.

Discussion
Communication to the base population was clear, concise, and consistent to minimize confusion and rumors among troops, and maintained in strict adherence to operational security guidelines. A standard briefing was provided to the commanders, with medical representatives attending each briefing to answer questions at the end. Commanders were instructed to brief the presentation in its entirety before opening up to questions. This prevented disruption of the flow and thought process in a field somewhat unfamiliar to the nonmedical commanders.

Shot lines were kept to a minimum, with efficient
scheduling to distribute the groups evenly during a 6-day workweek. Challenges, such as cold chain of custody with refrigeration of the vaccine, were overcome by organized process in three centralized locations. There was one power failure (not unusual in deployed locations) during the first week of immunization. Fortunately, no vaccine was lost, as the refrigeration was only down for a short time. Temperatures were monitored regularly in alarmed refrigerators.

Limitations of this study include the snapshot look at a military population, lack of generalizability of the high compliance result, and dependence on unit rosters. There may have been individuals assigned to special operations who were not included in submitted databases. There was no long-term follow-up. Although a small percentage received the vaccine from a previous injection, we did not report or record that percentage.

A major advantage of our findings is the report of actual numbers in a defined population. Another advantage of this report is potential generalizability to the US population (with confounders, healthy population considered) regarding lack of serious adverse effects and lack of reaction with the influenza vaccine.

Conclusion
We describe our preliminary experience in a mass immunization process in our deployed location to help guide future similar programs. Basic Public Health Department premises, such as collaboration with public affairs and integration of top leadership, are key to the success of any preventive medical venture. Commander ownership with clear communication and education in organized forums minimized misunderstandings while maximizing compliance. To our
knowledge, there were no reports of adverse effects resulting from the combination of the flu and anthrax vaccines.

The existing bioterrorism threat became more of a reality to the world with the anthrax attacks in the United States in 2001, which probably contributed to the success of the program. We believe the high compliance rate was also due to the fact that the program was driven by commanders and tracked with administrative action. Clear, concise communications through a standardized briefing by commanders minimized confusion and helped to maximize compliance. Availability of medical consultation several days in advance allowed for questions and concerns to be addressed with time to consider consequences, risks versus benefit, allergy testing, etc. Commanders informed military members that questions and concerns about the shot should be addressed ahead of time and that showing up for the vaccination indicated all questions and concerns had been addressed, thus minimizing delays. Lessons learned from successful mass immunization programs may help in planning similar preventive measures in the future (eg, smallpox vaccine).

References