DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

FEB 17 2004

AFEB

MEMORANDUM FOR Deputy Assistant Secretary of Defense for Health Affairs (Clinical and Program Policy)

SUBJECT: Periodic Report - DoD Smallpox Vaccination Program Evaluation 2004 - 1

1. References:

(a) Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 18 November 2003, Sentinel Case Review 2004 - 01.

(b) Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 18 February 2003, Periodic Report - DoD Smallpox Vaccination Program Evaluation.

(c) Memorandum, Deputy Assistant Secretary of Defense, Clinical and Program Policy, 8 January 2003, Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program.

(d) Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 8 January 2003, Smallpox Vaccination Evaluation Workgroup.

2. On 5 December 2002, the Assistant Secretary of Defense for Health Affairs requested the Armed Forces Epidemiological Board (AFEB) establish an independent workgroup of its members to evaluate the DoD Smallpox Vaccination Program (SVP) and provide, through the full Board, a periodic smallpox vaccination program implementation evaluation. The initial evaluation was submitted on 18 February 2003.

3. Since early January 2003, workgroup activities have continued in collaboration with a similar workgroup of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP). This combined AFEB-ACIP smallpox vaccination program workgroup (SVP-WG) has provided continuous evaluation of safety data from both the DoD and civilian smallpox vaccination program. The SVP-WG mission is to evaluate (a) data on vaccine safety (b) the vaccine safety monitoring and treatment system of the civilian and DoD smallpox vaccination programs and (c) monitor safety data on vaccinia immune globulin (VIG) and cidofovir used under investigational new drug protocols.

4. The AFEB-ACIP SVP-WG activities have included weekly teleconferences that first begin on

January 24, 2003, a face-to-face meeting on March 20-21, 2003, in Chicago to define trigger points for action and begin work on case definitions, and an ACIP teleconference on March 28, 2003, culminating in the first ACIP-AFEB SVP WG chair report. This work resulted in an ACIP recommendation that persons with known cardiac disease or $\geq$3 cardiac risk factors be deferred from receipt of smallpox vaccine. On June 18, 2003, a second report from the workgroup chair was delivered, specifically addressing cardiac events. This report concluded that there is biological plausibility for a causal relationship between smallpox vaccination and ischemic cardiac events, but the data were inadequate to definitively accept or reject such a relationship. Supporting analysis by DoD showed no elevation of risk. Regarding inflammatory cardiac events, the SVP-WG concluded that DoD data show a risk for myocarditis after smallpox vaccination that is significantly higher than background rate, and suggest a causal association between inflammatory heart disease and vaccination is likely. The ACIP subsequently recommended that due to these findings it did not support expanding the civilian program beyond the ACIP's pre-event smallpox vaccination recommendations.

5. After this report, cardiomyopathy was diagnosed in several persons between three and five months after smallpox vaccination. This led to the addition of a heart failure expert to the SVP-WG, completion of a review of the utility of searching for unidentified/adventitious infectious agents in vaccine or vaccines, and a sentinel case review process undertaken by five subgroups on the following subjects:

a. Unreviewed deaths
b. Dilated cardiomyopathy
c. Chest Pain/dyspnea/fever syndromes
d. Neurological adverse events
e. Dermatology

Reports by these subgroups have been completed or are in the process of completion.

6. It is anticipated the AFEB-ACIP SVP-WG will discontinue further deliberations unless there are new developments or changes to the DoD or DHHS smallpox vaccination programs. Current efforts focus on finalizing subgroup reports, identifying areas that have been inadequately addressed, and developing an interim summary. A summary report will be presented by the Chair to the February 2004 ACIP meeting, provided in parallel to the AFEB, with a full report to follow.

7. From the beginning of the current smallpox vaccination effort, DoD adopted identical screening and exemption criteria used by civilian authorities. A rigorous evaluation process has been used for continuous program improvements. After any serious adverse event following vaccination, DoD

has reassessed procedures and used independent panels of subject matter experts to assist as needed. Highlights of the DoD program to date include no recognized cases of eczema vaccinatum, progressive vaccinia, fetal vaccinia, or transmission of vaccinia within healthcare or other occupational settings.

8. In contrast, the occurrence of myopericarditis following vaccination was an unanticipated finding. Myopericarditis has been a rare or unrecognized event after smallpox vaccinations with the New York City Board of Health strain of vaccinia virus (Dryvax®, Wyeth Laboratories, Marietta, PA). These cases were identified either through sentinel reporting to military headquarters, systematic surveillance using the Defense Medical Surveillance System or reports to the Vaccine Adverse Event Reporting System. Current data from the DoD program indicate an attributable incidence of at least 140 clinical cases of myopericarditis per million primary smallpox vaccinations with Dryvax. A total of 58 males and one female aged 21 to 43 years were identified with confirmed or probable acute myopericarditis following vaccination of 492,730 personnel from December 15, 2002, through September 30, 2003. The cases were predominantly male (98.3 percent) and white (88.1 percent), both statistically significant associations ($p<0.05$). The observed incidence (16.11 per 100,000 persons) of myopericarditis over a 30-day observation window among primary vaccinees was nearly 7.5-fold higher than the expected rate of 2.16 per 100,000 (95 percent CI: 1.90, 2.34) among non-vaccinated active duty military personnel. The incidence of 2.07 per 100,000 persons among revaccinees was statistically similar to the expected background rate. These findings were published in the peer-reviewed literature in June 2003[1,2] with an additional manuscript under review.

9. DoD established and works with the CDC to maintain a joint pregnancy registry that now has enrolled over 160 women with vaccinia-exposed pregnancies. The anticipated rate of exposed pregnancies in the absence of screening and education is estimated to be 8 – 12 per 1,000 vaccinated women. The recognized rate of exposed pregnancies is < 2 per 1,000 vaccinated women, and this low rate reflects the use of history-screening at all DoD sites using smallpox vaccine. About 70% were vaccinated pre-conception or post-conception but before pregnancy was potentially identifiable through standard testing. Outcomes of most of these pregnancies will be known by the spring of 2004. To date, the rates of spontaneous abortions and ectopic pregnancies do not appear to be higher than anticipated for age and risk history. Vaccinia has not been identified in any tested products of conception. The Board strongly supports the work being done by the Naval Health Research Center, particularly Commander Margaret Ryan, USN, in support of the pregnancy registry.

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[1] Halsell JS, Riddle JR, Atwood JE, Gardner P, Shope R, Poland GA, *et al.* Myopericarditis Following Smallpox Vaccination Among US Military Personnel. *JAMA* 2003;289:3283-3289

[2] Grabenstein JD, Winkenwerder W Jr. US military smallpox vaccination program experience. JAMA 2003;289(24):3278-82.

10. The Board acknowledges the findings of the U.S. General Accounting Office (GAO-04-215R) evaluating the DoD smallpox vaccination program entitled "Smallpox Vaccination: Review of the Implementation of the Military Program" released on December 1, 2003.

11. The Board makes the following findings and recommendations supplementing the initial report concerning the smallpox vaccination program review to date:

a. We commend DoD for the early recognition of myopericarditis as an unanticipated adverse event following smallpox vaccination and for quick actions to inform clinicians, the medical community and the public about this complication. The Board supports the activities that have been undertaken or are planned regarding the myopericarditis findings. These include (1) comprehensive clinical follow-up guidance to clinicians evaluating post vaccinia myopericarditis cases (2) a registry of post vaccinia myopericarditis cases to monitor the clinical course of disease and (3) a case-control study to examine in greater detail potentially associated risk factors for myopericarditis among smallpox vaccinees. The Board considers it essential to continue clinical evaluation of existing cases to determine whether there will be any long-term morbidity associated with post-vaccinial myopericarditis and to conduct future vaccination programs in a way that allows for education, screening, and appropriate clinical follow-up to ensure evaluation, diagnosis, and treatment of suspected postvaccinial myopericarditis cases.

b. The Vaccine Healthcare Center (VHC) network has been an essential component that supported the development, testing, iterative refinement and implementation of the tools and educational materials for the vaccination program as well as the content clinical guidelines that have been an essential component of the successful implementation of the DoD-SVP. The network provides for individual case management, ongoing evaluation of adverse events, establishment of a clinical registry of myopericarditis cases, and development and support of clinical guidelines and clinical consultation. It is important that adequate funding for the VHC Network be secured quickly to capitalize on its early successes and allow its growth and maturation.

c. Data from a short-term cohort study of thousands of smallpox vaccinees has been collected analyzed and published. Expected temporary symptoms occurred after vaccination, notably itching, muscle ache, "feeling lousy," headache, swollen lymph nodes, irritation from bandages, subjectively reported fever, and local rash.

d. Standard documentation was used to record screening results, vaccination delivery, vaccination response, and adverse event management. Vaccination was recorded electronically as a component of the individual's longitudinal health record, which was maintained as part of the Defense Medical Surveillance System (DMSS). This system integrates data from sources worldwide in a continuously expanding relational database that documents the military and medical

experiences of service members throughout their careers. The DMSS allows nearly instantaneous assessments of the morbidity experiences of service members who share common characteristics, such as vaccination. The capabilities and analysis using DMSS has been critical in assessing the health outcomes associated with smallpox vaccination. It remains important to assess the electronic capture of theater health encounter data and institute appropriate action to ensure recording and availability of this information to the extent possible for future analysis.

e. The US Army Center for Health Promotion and Preventive Medicine (USACHPPM) is to be commended for evaluating the effectiveness of the DoD health risk communication program for smallpox vaccine administration. The USACHPPM published their findings in Final Report, "Results of the DoD Smallpox Vaccination Program Focus Groups Effort." The Board concurs with the findings from this report and recommends widest dissemination and implementation of the report recommendations.

f. The Board acknowledges the significant planning, organization and execution efforts which went into the smallpox vaccination program under a compressed timeline and very difficult operational circumstances and tempo. The Board fully concurs with the following statement by Wright and Fauci (Smallpox Immunization in the 21st Century: The Old and the New, *JAMA*. 2003;289:3306-3308): "By rapidly sharing the data from their smallpox vaccination experience with the general medical community, the Department of Defense has provided the civilian population with critical information pertaining to an important general public health issue and should be commended for this effort. This is a model for how military and civilian cooperation can effectively serve the public health of the entire nation." We wish to acknowledge the work of Colonel John Grabenstein and the Military Vaccine (MILVAX) Agency for their unparalleled commitment and ongoing professional management of the program.

g. The experience with the smallpox vaccination program to date suggests it is an important and effective force protection measure, and the Board supports continuation of the current risk-based approach for protection against smallpox. The Board should be informed if any changes to the current program are proposed in order to provide appropriate feedback and input.

12. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

STEPHEN M. OSTROFF, MD
AFEB, President

GREGORY A. POLAND, MD
Chair, Smallpox Evaluation Workgroup

AFEB
SUBJECT: Periodic Report - DoD Smallpox Vaccination Program Evaluation 2004 - 1

3 Enclosures
1. Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 18 February 2003, Periodic Report - DoD Smallpox Vaccination Program Evaluation
2. U.S. General Accounting Office (GAO-04-215R) "Smallpox Vaccination: Review of the Implementation of the Military Program"
3. USACHPPM Final Report, "Results of the DoD Smallpox Vaccination Program Focus Groups Effort"

CF:
MILVAX Agency

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FEB 18 2003

MEMORANDUM FOR Deputy Assistant Secretary of Defense for Health Affairs (Clinical and Program Policy)

SUBJECT: Periodic Report - DoD Smallpox Vaccination Program Evaluation

1. References:

(a) Memorandum, Deputy Assistant Secretary of Defense, Clinical and Program Policy, 8 January 2003, Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program.

(b) Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 8 January 2003, Smallpox Vaccination Evaluation Workgroup.

2. On 5 December 2002, the Assistant Secretary of Defense for Health Affairs requested the Armed Forces Epidemiological Board (AFEB) establish an independent workgroup of its members to evaluate the DoD Smallpox Vaccination Program (SVP) and provide him, through the full Board, a periodic program implementation evaluation. This evaluation is to include a review of the clinical experience of smallpox vaccine recipients and evaluation of the data collection methods and analysis, both short and long-term. The AFEB workgroup is to work collaboratively with a similar workgroup of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), in evaluating safety surveillance aspects of smallpox vaccination, both for the DoD SVP and for the national smallpox vaccination program. This DoD effort (coordinated with CDC's ACIP) is separate from the national smallpox vaccine program review being performed under CDC contract by the Institute of Medicine. On 8 January 2003 a select subcommittee of the AFEB was formally appointed and met by teleconference. This subcommittee has been reviewing DoD smallpox vaccine safety data weekly, and since 24 January has been meeting weekly in joint session with CDC's ACIP workgroup. The joint workgroup is developing a standard format for monitoring adverse events along with approximations of expected frequencies of adverse events developed from historical data, and is developing standard case definitions for the expected events. The Institute of Medicine's Committee on Smallpox Vaccination Program Implementation Board on Health Promotion and Disease Prevention commended this joint effort noting that this sharing of information and pooling of scientific resources can only improve the success of the national vaccination program and increase the chances of the safest smallpox vaccination program possible.

3. On 13 December 2002, the President directed smallpox vaccinations for about 500,000 selected military personnel. Comprehensive training programs in vaccination technique, infection-control safeguards, screening and education methods, adverse event monitoring, and product storage and handling had been launched in October 2002, and hence DoD vaccinations began immediately for select epidemic response personnel and hospital staff members. Detailed clinical and administrative policy was developed prior to program implementation and the AFEB has previously reviewed and provided comment on the clinical policy document. Prior to program implementation the DoD established a Military Vaccines Web Site (www.vaccines.army.mil), as well as a dedicated Smallpox Vaccination Program website (http://www.smallpox.army.mil) that provides access to current immunization program information for the DoD and the Military Services. In early January 2003, DoD began smallpox vaccinations of selected U.S. military forces and emergency-essential civilians and contractors deployed or deploying in support of U.S. Central Command missions. The DoD program is a mandatory occupational program. Statistics currently being reviewed by the workgroup are almost exclusively military with the exception of a few hundred DoD civilians, mostly hospital workers. The DoD smallpox program vaccine is Wyeth Dryvax, with 1.012 million doses released by the Food and Drug Administration (FDA) and transferred to DoD by CDC. Approximately 702,300 doses have been fielded at 257 locations. Vaccinia Immune Globulin (VIG) for intramuscular (IM) administration is being used as an Investigational New Drug (IND) with 4,350 vials of the IM product on hand. From this stock, 128 vials have been fielded at 5 locations worldwide. The remaining stocks are centrally maintained. This is adequate VIG-IM to support approximately 550 treatments. An additional IND protocol for an intravenous form of VIG will be submitted to the FDA in the coming months.

4. The DoD has proposed using a mutually supporting set of active and passive surveillance and reporting systems along with specific studies to assess the safety of smallpox vaccinations. These studies include:

(a) Description of DoD personnel exempted from smallpox vaccination.

(b) Description of acute responses after DoD smallpox vaccination: "take" rates, as well as symptoms, sick-call visits, and duty limitation within the first 7 and 30 days post-vaccination, among a limited subset of vaccinees.

(c) Rates of outpatient visits, contrasting smallpox-vaccinated and unvaccinated DoD personnel.

(d) Surveillance for sentinel medical events of note, based on DoD requests for vaccinia immune globulin (VIG) or cidofovir, or referrals to the Vaccine Healthcare Center Network.

(e) Surveillance for significant sentinel medical events, based on reports to the Vaccine Adverse Events Reporting System (VAERS), from both military and civilian sources. DoD will solicit VAERS reports from its providers and vaccine recipients. CDC's VAERS staff will evaluate reports received from all sources and will provide the data to DoD to ensure total visibility of events among DoD vaccine recipients. VAERS staff will investigate all reports involving hospitalization and deaths and will trigger case-control or other investigations if the number of reports for a given diagnoses exceeds a threshold of temporally expected events.

(f) Evaluation of smallpox-vaccinated DoD personnel with respect to inpatient and outpatient visits, using the Defense Medical Surveillance System (DMSS), with potential use of comparison studies using data from un-vaccinated personnel.

(g) Coordination with CDC in establishing a prospective registry of individuals inadvertently immunized to include: women inadvertently vaccinated before recognition of pregnancy, and persons who otherwise had a contraindication to receiving vaccine. DoD will encourage enrollment of individuals into the registry, once established. In the interim, DoD officials are maintaining data on women inadvertently vaccinated, so that they can be quickly enrolled in the registry. As of this report, four women have been identified as pregnant at the time of vaccine administration.

5. DoD smallpox vaccine recipients have experienced the temporary symptoms expected after smallpox vaccination (e.g., itching, swollen lymph nodes, fever, malaise). Additionally, several dozen-vaccine recipients have developed "flat" rashes that, although not clinically significant or contagious, require differentiation from disseminated vaccinia. These individuals have been treated symptomatically and have remained on the job with their units. These rashes are consistent with known responses after smallpox vaccination. Since mid-December 2002, about 3% of vaccinated personnel have needed to take time off from work for an average of 1.5 days. Time off after primary (first) vaccination has been more common (4% to 5%) than after revaccination (1% to 2%). In early February 2003, the first case of auto-inoculation was identified, a case of limbal keratitis, treated as an outpatient, who had no corneal scarring. To date, no cases of contact transfer of vaccinia virus have been identified and no one has required treatment with vaccinia immune globulin (VIG). There have been three noteworthy adverse events reported to the workgroup as of 7 February 2003:

- On January 26, a U.S. Army soldier was admitted with a diagnosis of encephalitis in an overseas military hospital. The 23-year-old male had been vaccinated against smallpox prior to deployment. He became ill eight days after the vaccination and was medically evacuated to a military hospital for treated. Diagnostic studies did not establish vaccinia virus or another virus or bacteria as a cause of the peri-infectious encephalitis, but the temporal relationship is circumstantial evidence. At present, although an exact case definition for post-vaccinal encephalitis or

encephalomyelitis has yet to be agreed upon, smallpox vaccination has been assumed to be the cause of the peri-infectious encephalitis. The soldier has recovered completely and has been discharged from the hospital and returned to duty. Information about the case was shared with civilian health authorities shortly after the situation was recognized. The workgroup examined background information about rates of encephalitis after smallpox vaccinations from four studies published during 1963 and 1968. In these studies, the rate of encephalitis after primary smallpox vaccinations administered to persons 20+ years old ranged from 0 to 3.472 cases per million vaccinations. Using a variety of statistical techniques, the workgroup concluded that the observed rate calculated using this single case is not statistically significantly greater than the expected rate.

- On January 25, a U.S. Army soldier at a U.S. base developed a rash on the trunk and back approximately 10 days after smallpox vaccination that included several pustules (pus-filled blisters). The 30-year-old man's rash appears to qualify as "generalized vaccinia," one of the expected and somewhat rare skin reactions after smallpox vaccination. Generalized vaccinia can sometimes develop into a serious skin condition. But in this case, the soldier is well and continues to work at his usual location. Again, information about the case was shared promptly with civilian health authorities. Two additional cases of mild pustular rash conditions that may qualify as generalized vaccinia have also been recognized in two members of the U.S. Air Force. Like the first case, these airmen were treated as outpatients and have remained on the job. These three rash diagnoses do not appear to meet a draft case definition of "true" generalized vaccinia being developed by CDC and DoD. Final categorization of these cases will be made once the consensus case definition for generalized vaccinia is published.

- On February 5, a 26-year-old U.S. Air Force airman developed chest pain and went to a U.S. emergency room for treatment. This visit occurred 11 days after smallpox vaccination. After a series of tests, this individual was diagnosed with a heart condition called acute myocarditis. Studies of military recruits from Finland in the 1970s and 1980s have associated acute myocarditis with a European strain (but not the strain used in the United States) of smallpox vaccine, with prompt recovery and no long-term problems reported as the usual sequela. Information about this case was shared with civilian health authorities shortly after the situation was recognized. The individual recovered within a few days and is being readied for discharge from the hospital. Because of the background rate of acute myocarditis, sometimes associated with respiratory viral infection, a comprehensive clinical workup is required on such cases including acute and convalescent titers for viral infection.

The joint workgroup is working to develop case definitions for the expected smallpox vaccination adverse events along with diagnostic algorithms to assist clinicians in clinical evaluation of these cases.

6. The Board makes the following findings and recommendations concerning the smallpox vaccination program review to date:

(a) The DoD has developed and promulgated a comprehensive post-event smallpox response plan. The DoD smallpox response plan provides detailed guidance to commanders and is based upon the CDC Smallpox Response Plan. The plan addresses military-unique situations and covers both ring vaccination and wide-area vaccination.

(b) DoD clinical policies are consistent with the FDA, CDC and ACIP guidelines. Administrative guidelines have been developed for DoD program execution and individual military service implementation plans provide local program execution guidance.

(c) Extensive training was initially provided to DoD health care workers and training is ongoing. Hands-on training for medical providers was initially provided at a DoD Smallpox Preparedness Conference held in late October with three levels of vaccination training available on the Smallpox Vaccination website. Cascade training by military services has been provided regionally and other distance-learning products (e.g., CD-ROM) are available. Training has also been incorporated into curricula at military academic centers. As new training products become available or updates necessary in existing products, the SVP Office is making them available.

(d) The clinical documentation policy is comprehensive. For initial screening, a common screening form is used by all military services. Contraindications to vaccination are recorded in each individual's medical record. A record of smallpox vaccine administration is recorded in both the individual's medical record and in a centralized computer tracking system. Adverse events are required to be recorded in medical records and on VAERS reports and patient access to regional Vaccine Healthcare Centers (VHC) is available. Follow-up evaluation of vaccination take to include a clinical evaluation is standard and a common assessment form has been developed for clinical evaluation of adverse events. However, it is uncertain if the documentation policy is uniformly being followed and the standard forms are being used and are available in the individual's medical record, as no quality assurance data are currently available. Given the importance of accurate screening for contraindications and the DoD's record for accurately recording immunization history, it is important to have an ongoing program of quality assurance. The Military Services have been tasked with establishing quality assurance programs and auditing records, but audit results are not yet available. Given the rapidity of program implementation, these audits should be ongoing and the data available for review by the SVP Office.

(e) The program implementation has been appropriately staged with Smallpox Epidemic Response Teams, medical teams for hospitals and clinics, and mission critical forces currently being vaccinated. The rapidity of program implementation however, presents inherent obstacles in timing of the vaccination, follow-up and potential management of adverse events.

(f) The proposed active and passive surveillance and reporting systems and specific studies to assess the safety of smallpox vaccinations and quality assurance of the program appear adequate, but are yet to be fully resourced. With the compressed time-line for vaccination, it is important to have quality assurance programs in place and data available for review on an expeditious basis.

- Data from the proposed short-term cohort study of thousands of smallpox vaccinees have been collected, but currently only a very small fraction of these data have been analyzed. Such data are necessary to provide information on the rate of common but mild adverse events during the first few weeks following vaccination.

- All VAERS reports for smallpox vaccine adverse events (both military and civilian sector) are being centrally collected and analyzed at CDC and the data presented to the joint ACIP-AFEB workgroup. Critical to this process is presentation of a detailed clinical case review of significant adverse events. Historical data are being analyzed by the workgroup to establish nominal trigger points and case definitions are being developed for expected adverse events. The numerous differences between experience in the 1960s and today make simple statistical projections tentative. VAERS data for DoD vaccinees is additionally being centrally collected and analyzed as part of the overall DoD enhanced surveillance for smallpox vaccine adverse events. The joint workgroup is reviewing these data on a weekly and as needed basis.

- Analysis and reporting of health encounter data among vaccinees compared to unvaccinated individuals using data available in the Defense Medical Surveillance System (DMSS) has not yet been performed, because of the time interval necessary for data to accumulate within the DMSS. As many individuals are being immunized as part of the current deployment or while deployed to the Central Command theater of operations, it is uncertain if all encounter data will be captured as part of the electronic inpatient or outpatient medical record, and thus available for analysis. The Military Services should assess the electronic capture of theater health encounter data and institute appropriate action to ensure recording and availability of this information to the extent possible for future analysis.

- Studies evaluating the effectiveness of the DoD health risk communication program for smallpox vaccine administration have not been resourced and initiated and thus no data have been presented to the workgroup.

- Plans for long-term evaluation by the Naval Health Research Center to investigate the rate of smallpox vaccine-related chronic and subjective outcomes are yet to be resourced and/or developed given the recent initiation of the SVP.

- Plans to investigate adverse birth outcomes among infants born to women inadvertently immunized for smallpox have been presented to the workgroup. The DoD proposed to the CDC in early December 2002 that the CDC establish a registry for short and long-term

follow-up of individuals inadvertently immunized to include pregnant women. DoD, through the Naval Health Research Center's Birth and Infant Health Registry, has actively partnered with CDC in this effort and will vigorously market the availability of the registry as soon as CDC is ready to receive data. However, it remains unclear specifically how the DoD and CDC will identify and encourage participation in this registry such that more than the expected few individuals who may allege an adverse response from smallpox vaccinations will participate. Epidemiologically, it is necessary to enroll in the registry most all such inadvertent vaccine recipients such that those with adverse outcomes may be compared to those who were also exposed but have no adverse outcomes.

- A process review should be expeditiously accomplished on all cases of inadvertent vaccine administration including administration to pregnant women in order to identify program lapses, potential requirements for program modification, and lessons learned for dissemination to all DoD vaccination sites.

(g) Upon review of the limited available data, early vaccination program feedback is positive. Based upon limited data from over 100,000 individuals vaccinated through early February 2003, approximately 60 percent have been primary vaccinees and 40 percent have been previously vaccinated. This ratio is increasingly shifting in favor of primary vaccinees. Exemptions have ranged from 10 to 40 percent (includes both administrative and clinical exemptions), depending upon the site. The take rate has been 96 percent for primary vaccination (3 jabs) and 99 percent for revaccination (15 jabs). Adverse events have included the expected temporary reactions normally observed with the Wyeth Dryvax vaccine. The DoD safety experience with smallpox vaccinations to date is consistent with what was to be expected overall.

(h) As the program moves forward, the need to process vaccination survey data in order to answer analytical morbidity questions and assess the nature and completeness of individuals being exempted for medical reasons in a timely fashion will be critical. This will require having screening data available in an automated and easily analyzed fashion. It will be important to not underestimate the software and computer support and resources needed and to avoid delays inherent with purchase of necessary licenses and equipment.

(i) Data to validate accurate recording of the smallpox immunization and follow-up, both in the medical record and the electronic record, have not been presented to the workgroup. Quality assurance of program documentation should be ongoing to ensure the automated immunization tracking system data are complete and reflect accurately the immunization history of the individual. The Military Services should expedite quality assurance review of the SVP execution.

(j) Given existing resources, the MILVAX Agency is currently and appropriately focusing efforts on the exceptional cases, ensuring the most critical information is known. However, the long-term program success may depend upon the ability to recognize less noteworthy adverse

events and potential adverse trends among vaccinees, which may not immediately impact program execution, but must be recognized quickly and appropriate action taken. This may necessitate that additional resources be assigned to the MILVAX Agency to assist with data entry and epidemiological analysis. The mix of personnel should reflect the tri-service nature of the program.

(k) While prophylactic administration of VIG to prevent complications from smallpox vaccination is not routinely recommended, there may be occasional circumstances where persons with contraindications to vaccination (due to immune suppression, pregnancy, or other reasons) may inadvertently be vaccinated and where consideration should be given for use of VIG. Current INDs were developed for use of VIG as treatment of complications. To cover situations where prophylactic use may be indicated, DoD could apply for individual compassionate use INDs for each situation. However, an alternate approach would be to develop a separate IND, which defines time frames and circumstances where prophylactic use should be considered. This IND submission should be done in coordination with CDC. This would add another option for therapy that may be life saving, and has little risk to the individual. The Board therefore recommends that DoD proceed expeditiously with development and submission of an IND protocol to allow for prophylactic VIG use if indicated.

(l) The workgroup is currently planning, at the earliest convenience, a visit to a vaccination site to observe the smallpox vaccination process.

The DoD is to be commended for planning, organizing and executing a comprehensive smallpox vaccination program given the compressed timeline and establishing a joint effort with the CDC to independently assess and monitor on an ongoing basis the safety of the smallpox vaccine and independently evaluate the DoD smallpox vaccination program. Colonel John Grabenstein is to be commended for his unparalleled commitment and ongoing professional management of the program.

AFEB
SUBJECT: Periodic Report - DoD Smallpox Vaccination Program Evaluation

7. The above recommendations were unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

STEPHEN M. OSTROFF, MD
AFEB, President

GREGORY A. POLAND, MD
Chair, Smallpox Evaluation Workgroup

2. Enclosures
1. Memorandum, Deputy Assistant Secretary of Defense, Clinical and Program Policy, 8 January 2003, Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program.
2. Memorandum, Executive Secretary, Armed Forces Epidemiological Board, 8 January 2003, Smallpox Vaccination Evaluation Workgroup.

CF:
MILVAX Agency

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

JAN - 8 2003

HEALTH AFFAIRS

MEMORANDUM FOR EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program

On December 5, 2002, as detailed in the attached document, Dr. Winkenwerder asked the Armed Forces Epidemiological Board (AFEB) to establish an independent workgroup of its members to evaluate the DoD Smallpox Vaccination Program (SVP) and provide to him, through the full board, a periodic program implementation evaluation. This evaluation should include a review of the clinical experience of smallpox vaccine recipients and evaluation of the data collection methods and analysis, both in the short and long-term. Dr. Winkenwerder expects the AFEB workgroup to work collaboratively with a similar workgroup of the CDC's Advisory Committee on Immunization Practices (ACIP), in evaluating safety surveillance aspects of smallpox vaccination, both for the DoD SVP and for smallpox vaccinations given in the civilian sector. This DoD effort is separate from the civilian smallpox vaccine program review being performed by the Institute of Medicine.

This AFEB-ACIP joint workgroup would be expected to meet at least monthly by teleconference and formally on a quarterly basis. More frequent meetings may be necessary as determined by the needs of the DoD, CDC and the workgroup. Funding for the AFEB workgroup travel and other expenses associated with this tasking will be provided to the AFEB Executive Secretariat at a later date. The Military Vaccine Agency will provide program status updates to the workgroup. The Vaccine Health Care Center Network will report on clinical investigations of adverse events. The Army Medical Surveillance Activity (AMSA) will report on ongoing surveillance and analysis of ambulatory and inpatient experiences among smallpox vaccine recipients. The Medical Materiel and Research Command will provide information on any use of vaccinia immune globulin or cidofovir under their investigational new drug protocols.

My point of contact is LtCol Roger Gibson, Program Director for Military Public Health, who may be reached at 703-681-1703 x5211 or email roger.gibson@ha.osd.mil.

David N. Tornberg, MD, MPH
Deputy Assistant Secretary of Defense
Clinical and Program Policy

Attachment:
As stated

cc:
DASD, FHP&R
Army Surgeon General
USA AMSA
Vaccine Health Care Center
USA MRMC

Recommendations for Enhancing Smallpox Vaccine Adverse Event Surveillance

The following recommendations, if implemented, would significantly enhance smallpox vaccine adverse-event surveillance.

1. Establish a common smallpox vaccine analyzable medical note for all Services and ensure that the data are collected in scannable format for conversion to electronic databases. Such a tool would allow for the identification of medically exempt Service members. The ability to collect exemption and vaccination information electronically would also support smallpox vaccine programmatic evaluation.

   Recommended Office of Primary Responsibility (OPR): Military Vaccine Office (MILVAX)
   Requirement: Analyzable medical note/screening tool
   Cost and/or recommended funding source: Within MILVAX Operational Budget

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

2. Direct the development of a small short-term cohort study of smallpox vaccinees. Such a study could provide critical information on the rate of common but mild adverse events or the first few weeks following immunization. Using the cohort, researchers could assess the effectiveness of the health risk communication message and medical screening process associated with the smallpox immunization.

   Recommended OPR: MILVAX
   Requirement: Short-term cohort study
   Cost and/or recommended funding source: Additional TDY funding and staffing. Estimated $250,000 (Subject to coordination with HBFP)

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

3. Create policy implementing Vaccine Adverse Events Reports System (VAERS) reporting procedures for all vaccines consistent with those employed for anthrax vaccine. While adverse reactions to smallpox and anthrax vaccines are of high importance to DoD, the ability to centrally collect information on all vaccine-related adverse events would significantly enhance DoD surveillance capabilities.

   Recommended OPR: OASD (HA) C&PP
   Requirement: VAERS policy document
   Cost and/or recommended funding source: None

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

4. Direct the establishment of adverse vaccine event investigation teams (coordinated through the Vaccine Healthcare Center (VHC) Network) which can be called upon to conduct thorough and complete evaluations and consultations of severe and other events of interest such as instances when vaccinia immune globulin or cidofovir is used. The team should include epidemiologists, rheumatologists and other clinicians with the training needed to conduct such investigations.

   Recommended OPR: VHC Network, in collaboration with U.S. Army Medical Research Institute of Infectious Diseases, U.S. Army Medical Research and Materiel Command and Uniformed Services University of the Health Science.
   Requirement: Smallpox vaccine adverse event investigation team
   Cost and/or recommended funding source: Additional travel costs and staffing. The National Vaccine Program Office (NVPO) may also serve as a funding opportunity for clinical studies and clinical research proposals.

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

5. Create policy to directly task Defense Medical Surveillance System to provide routine reports on vaccine-related adverse-event rates, particularly military-relevant vaccines (e.g., anthrax, smallpox, yellow fever, influenza), comparing and contrasting vaccinated and unvaccinated people.

   Recommended OPR: OASD (HA) C&PP for policy and Army Medical Surveillance Activity for implementation
   Requirement: Policy/tasking document
   Cost and/or recommended funding source: None for policy. None for implementation

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

6. Direct the development of a process for programmatic review of the smallpox immunization plan to include an evidence-based evaluation of the effectiveness of health risk communication message. The programmatic review may be accomplished partially or fully in conjunction with a small short-term cohort study as described above.

   Recommended OPR: MILVAX
   Requirement: Programmatic review of smallpox immunization plan with analysis of health risk communication effectiveness
   Cost and/or recommended funding source: Additional costs and staffing. Estimated $500,000 (subject to coordination with HBFP)

   ASD (HA): APPROVE ✓ **DISAPPROVE**____

7. Direct the development of protocols to investigate the rate of smallpox vaccine-related chronic and subjective outcomes. This recommendation requires a long-term commitment but does not require immediate implementation. Conceptually, military Service members enrolled in the Millennium Cohort Study could form the cohort for this type of investigation.

   Recommended OPR: Deployment Health Research Center in collaboration with Uniformed Services University of the Health Sciences
   Requirement: Research on smallpox vaccine-related chronic and subjective outcomes
   Cost and/or recommended funding source: Estimated cost: $3M. Funding could be obtained through the Congressionally-directed Medical Research Program budget as a carve out

   ASD (HA): APPROVE____ DISAPPROVE____ WILL REVIEW LATER ✓

8. Direct the development of protocols to investigate adverse birth outcomes among live infants born to women who inadvertently received smallpox vaccine while pregnant.

   Recommended OPR: Deployment Health Research Center (currently investigating anthrax vaccine adverse related events)
   Requirement: Retrospective birth outcomes research
   Cost and/or recommended funding source: Estimated cost: $500K. Funding could be obtained through the Congressionally-directed Medical Research Program budget as a carve out

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9. Consider collaboration with Centers for Disease Control and Prevention (CDC) in the establishment of prospective registry for women who are found to have been pregnant at the time of smallpox vaccine administration. Such a registry will allow for prospective tracking of reproductive outcomes.

   Recommended OPR: Naval Health Research Center/Deployment Health Research Center
   Requirement: Prospective birth outcomes research
   Cost and/or recommended funding source: CDC

   ASD (HA): APPROVE ✓ **DISAPPROVE____**

10. Establish an independent external review board to evaluate the smallpox vaccination program, such as through collaboration between working groups of the Advisory Committee on Immunization Practices and the Armed Forces Epidemiological Board (AFEB). The Board should report to the ASD (HA).

Recommended OPR: MILVAX/AFEB
Requirement: External review board
Cost and/or recommended funding source: Undetermined-dependent of how the board is established

ASD (HA): APPROVE ✓ **DISAPPROVE**____

11. Based on data obtained through smallpox surveillance, establish a mechanism to facilitate and implement collaborative interagency research using state-of-the-art technologies and approaches. Examples of research opportunities include: genotyping analysis of families in which smallpox vaccine side effects are noted or perceived and the impact of concomitant administration of anthrax and smallpox vaccine.

Recommended OPR: VHC Network in collaboration with CDC
Requirement: Collaborative peer-reviewed research
Cost and/or recommended funding source: Dependent on protocol development and scope of specific research; multiple funding vehicles may be used

ASD (HA): APPROVE ✓ **DISAPPROVE**____

William Winkenwerder Jr.
5 December 2002

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

AFEB

January 8, 2003

MEMORANDUM FOR Select Subcommittee, Armed Forces Epidemiological Board

SUBJECT: Smallpox Vaccination Evaluation Workgroup

1. On 8 January 2003, the Assistant Secretary of Defense for Health Affairs requested the Armed Forces Epidemiological Board (AFEB) form a workgroup of its members to evaluate the DoD Smallpox Vaccination Program. Dr. Winkenwerder expects this AFEB workgroup to work with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) in evaluation of safety surveillance aspects of smallpox vaccination, both for the DoD Smallpox Vaccination Program and the for smallpox vaccinations given in the civilian sector. The DoD program review is separate from the civilian smallpox vaccine program review being performed by the Institute of Medicine. The AFEB members listed below have been appointed to this workgroup:

Pierce Gardner, M.D., F.A.C.P - Member
Gregory C. Gray, MD, MPH - Member
Gregory A. Poland, M.D. - Member
Robert Shope, M.D. - Member
Steven M. Ostroff, M.D. – Ex Officio Member

2. LTC(P) John Grabenstein will provide periodic program updates for the DoD and will facilitate presentation of necessary data. This AFEB-ACIP joint workgroup is expected to meet at least monthly by teleconference and formally on a quarterly basis. More frequent meetings may be necessary as determined by the needs of the DoD, CDC and the workgroup.

Encl

JAMES R. RIDDLE, DVM, MPH
Colonel, USAF, BSC
Executive Secretary

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

JAN - 8 2003

HEALTH AFFAIRS

MEMORANDUM FOR EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Collaboration with Advisory Committee on Immunization Practices to Evaluate Smallpox Vaccination Program

On December 5, 2002, as detailed in the attached document, Dr. Winkenwerder asked the Armed Forces Epidemiological Board (AFEB) to establish an independent workgroup of its members to evaluate the DoD Smallpox Vaccination Program (SVP) and provide to him, through the full board, a periodic program implementation evaluation. This evaluation should include a review of the clinical experience of smallpox vaccine recipients and evaluation of the data collection methods and analysis, both in the short and long-term. Dr. Winkenwerder expects the AFEB workgroup to work collaboratively with a similar workgroup of the CDC's Advisory Committee on Immunization Practices (ACIP), in evaluating safety surveillance aspects of smallpox vaccination, both for the DoD SVP and for smallpox vaccinations given in the civilian sector. This DoD effort is separate from the civilian smallpox vaccine program review being performed by the Institute of Medicine.

This AFEB-ACIP joint workgroup would be expected to meet at least monthly by teleconference and formally on a quarterly basis. More frequent meetings may be necessary as determined by the needs of the DoD, CDC and the workgroup. Funding for the AFEB workgroup travel and other expenses associated with this tasking will be provided to the AFEB Executive Secretariat at a later date. The Military Vaccine Agency will provide program status updates to the workgroup. The Vaccine Health Care Center Network will report on clinical investigations of adverse events. The Army Medical Surveillance Activity (AMSA) will report on ongoing surveillance and analysis of ambulatory and inpatient experiences among smallpox vaccine recipients. The Medical Materiel and Research Command will provide information on any use of vaccinia immune globulin or cidofovir under their investigational new drug protocols.

My point of contact is LtCol Roger Gibson, Program Director for Military Public Health, who may be reached at 703-681-1703 x5211 or email roger.gibson@ha.osd.mil.

David N. Tornberg, MD, MPH
Deputy Assistant Secretary of Defense
Clinical and Program Policy

Attachment:
As stated

cc:
DASD, FHP&R
Army Surgeon General
USA AMSA
Vaccine Health Care Center
USA MRMC

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   Recommended Office of Primary Responsibility (OPR): Military Vaccine Office (MILVAX)
   Requirement: Analyzable medical note/screening tool
   Cost and/or recommended funding source: Within MILVAX Operational Budget

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   Recommended OPR: MILVAX
   Requirement: Short-term cohort study
   Cost and/or recommended funding source: Additional TDY funding and staffing. Estimated $250,000 (Subject to coordination with HBFP)

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   Requirement: VAERS policy document
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   Recommended OPR: Naval Health Research Center/Deployment Health Research Center
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Recommended OPR: VHC Network in collaboration with CDC
Requirement: Collaborative peer-reviewed research
Cost and/or recommended funding source: Dependent on protocol development and scope of specific research; multiple funding vehicles may be used

ASD (HA): APPROVE ✓ **DISAPPROVE**_____

William Winkenwerder Jr.
5 December 2002

GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

December 1, 2003

The Honorable Susan M. Collins
Chairman
Committee on Governmental Affairs
United States Senate

Subject: *Smallpox Vaccination: Review of the Implementation of the Military Program*

Dear Chairman Collins:

On December 13, 2002, in response to growing concern that a terrorist or hostile regime might have access to the smallpox virus and attempt to use it against the American people, the President announced the formation of the National Smallpox Vaccination Program. The program has two components—one responsible for vaccinating civilians and another responsible for vaccinating military personnel. The Centers for Disease Control and Prevention (CDC) is responsible for implementing the civilian component of the National Smallpox Vaccination Program. The Department of Defense (DOD) is responsible for implementing the military component of the program.

Because the National Smallpox Vaccination Program is the nation's first large-scale bioterrorism defense program, you asked us to assess the implementation of the program in order to aid the development of future programs. In April 2003, we reported on the implementation of the civilian component of the National Smallpox Vaccination Program.[1] In this report, we describe (1) how DOD implemented its smallpox vaccination program and (2) the steps DOD took to facilitate the implementation of the program.

To describe how DOD implemented its smallpox vaccination program and the steps it took to facilitate the implementation of the program, we reviewed DOD's planning guidance for the program, implementation plans related to the program, training for vaccinators, and educational materials for vaccinees. We also reviewed CDC guidelines and documents related to the civilian program that were used in the military's smallpox vaccination program. We interviewed Army, Navy, Air Force, and Marine officials and reviewed written responses to our questions provided by the

[1]U.S. General Accounting Office, *Smallpox Vaccination: Implementation of the National Program Faces Challenges*, GAO-03-578 (Washington, D.C.: Apr. 30, 2003).

Army National Guard and the Coast Guard. We observed the vaccination process at Andrews Air Force Base. In addition, we reviewed the Institute of Medicine's recommendations and CDC's and DOD's policies for monitoring and recording adverse health events[2] following the vaccinations. We obtained information about adverse health events from DOD and CDC. We performed our work from April through November 2003 in accordance with generally accepted government auditing standards.

Results in Brief

DOD implemented its smallpox vaccination program in stages and took steps to prevent and monitor adverse health events following the vaccinations. The first stage of the smallpox vaccination program consisted of a pilot program that began in December 2002, during which DOD vaccinated and monitored the health of military personnel at four sites. According to DOD officials, the intent of the pilot program was to assess DOD's procedures for administering the vaccine and monitor the frequency of adverse health reactions. After completion of the pilot program, DOD began full implementation of the smallpox vaccination program in mid-January 2003. DOD vaccinated its personnel in stages—prioritizing its personnel according to which groups would be most likely to respond first to a smallpox outbreak. As of October 2003, DOD had vaccinated more than 500,000 military personnel. In order to minimize the number of people who might have adverse reactions to the vaccine, DOD followed CDC guidelines by screening personnel for health conditions that precluded them from receiving smallpox vaccinations. To monitor adverse health events following the vaccinations, DOD used two health information tracking systems, CDC's Vaccine Adverse Event Reporting System (VAERS) and DOD's Defense Medical Surveillance System (DMSS).

To facilitate its vaccination program, DOD took steps to ensure the availability of the vaccine and educate its personnel. Specifically, DOD established practices to limit the amount of vaccine that could be wasted or contaminated. For example, to ensure the vaccine was not wasted due to a loss of potency, its temperature was monitored with a computer chip to ensure that the vaccine was maintained at the proper temperature during shipment. DOD also facilitated the implementation of its vaccination program by educating its personnel—both those who administered the vaccine and those who received it—on related issues, such as vaccination procedures and potential adverse health reactions.

In commenting on a draft of this report, DOD agreed with our findings.

[2]In this report we use the term "adverse health event" to refer to a health condition that occurred after vaccination and may or may not be attributable to the vaccine. When adverse health events are diagnosed as causally related to the vaccine, we use the term "adverse health reactions."

Background

Smallpox is a contagious disease that is generally spread through prolonged face-to-face contact, but it can also be spread through direct contact with infected bodily fluids or contaminated objects. Smallpox symptoms include fever and a distinctive skin rash. There is no known cure for smallpox, and it is fatal in about 30 percent of cases. Immunity to the virus that causes smallpox—the variola virus—is conferred through inoculation with a vaccine made from the closely related vaccinia virus. After a worldwide effort of organized vaccinations, the World Health Organization declared, in May 1980, the world free of naturally occurring smallpox.

The health condition of those who receive the smallpox vaccine must be assessed before and monitored after vaccination. Before vaccination, potential recipients of the smallpox vaccine must be screened for contraindications, which are health conditions or symptoms that preclude vaccination. After vaccination, the vaccination site is monitored for a skin lesion, known as a "major reaction" or "take," which indicates a protective immune response. If the vaccination results in a take, a red itchy bump forms over the vaccination site within 2 to 4 days. Anyone who does not experience a take has to be revaccinated.

The smallpox vaccination may create side effects known as adverse reactions. These adverse reactions include temporary symptoms such as itching, fatigue, muscle ache, and swollen lymph nodes. More serious adverse reactions include accidental inoculation (localized rash elsewhere on the body), encephalitis (inflammation of the brain), generalized vaccinia (rash spread to the entire body), myocarditis or pericarditis (inflammation in or around the heart), and death. Because the vaccine uses live virus, an inadvertent transfer of vaccinia can occur in persons exposed to the vaccination site of someone who has recently received the vaccine. There are two drugs used to treat certain adverse reactions caused by the vaccine: vaccinia immune globulin (VIG) and the antiviral drug cidofovir.

Routine smallpox vaccinations were discontinued among U.S. children in 1972, and among U.S. healthcare workers in 1976. However, in contrast with the civilian sector, DOD continued to provide smallpox vaccinations to its troops. Between 1984 and 1990, smallpox vaccinations were only provided irregularly to recruits during basic training because there were shortages of VIG.[3] In 1990, DOD vaccinations were discontinued until the President announced the formation of the National Smallpox Vaccination Program in December 2002.

[3]In addition, smallpox vaccinations were not provided at some military facilities because some facilities lacked the ability to test for the human immunodeficiency virus (HIV), and DOD does not knowingly vaccinate personnel with HIV.

In administering the civilian component of the National Smallpox Vaccination Program, CDC updated the Smallpox Response Plan and Guidelines (CDC guidelines).[4] These guidelines include guidelines for recognizing contraindications and vaccine takes, administering and storing the vaccine, recognizing adverse reactions, administering VIG, and monitoring and reporting adverse health events information.

DOD designated the Department of the Army as responsible for overseeing the military component of the National Smallpox Vaccination Program. The Army's Military Vaccine (MILVAX) Agency was responsible for developing clinical guidelines for DOD that are consistent with CDC guidelines for the civilian component of the National Smallpox Vaccination Program. The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) was responsible for coordinating the distribution of the smallpox vaccine within DOD.

In September 2002, we reported on DOD's Anthrax Vaccine Immunization Program. Specifically, we reported on the limited availability of the vaccine and general dissatisfaction among military personnel with the completeness and accuracy of the information DOD provided about the anthrax vaccination program and the anthrax vaccine.[5]

DOD Implemented Its Smallpox Vaccination Program in Stages and Took Steps to Prevent and Monitor Adverse Reactions

DOD implemented its current smallpox vaccination program in stages and took steps to prevent and monitor adverse health events following the vaccinations. Prior to full implementation of its program in mid-January 2003, DOD conducted a pilot study during which it vaccinated and monitored the health of military personnel. DOD used CDC's clinical guidelines as a template throughout its smallpox vaccination program for establishing priorities for who would be vaccinated and for screening potential vaccinees for contraindications. DOD also monitored adverse health events following the vaccinations with information supplied by each of the services.

DOD's Smallpox Vaccination Pilot Program Preceded Wider Vaccinations

DOD initiated its smallpox vaccination program with a pilot program. In December 2002, DOD began the smallpox vaccination pilot program by vaccinating and monitoring healthcare personnel at four sites: Walter Reed Army Medical Center, Washington, D.C.; Aberdeen Proving Ground, Md.; Wilford Hall Air Force Medical Center, Lackland Air Force Base, San Antonio, Tex.; and the National Naval Medical Center, Bethesda, Md. According to DOD officials, the intent of this pilot program was to monitor vaccinee take rates and the frequency of adverse health reactions.

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[4]Centers for Disease Control and Prevention, *Smallpox Response Plan and Guidelines*, Draft 3.0 (Atlanta, Ga.: Sept. 21, 2002).

[5]U.S. General Accounting Office, *Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew*, GAO-02-445 (Washington, D.C.: Sept. 20, 2002).

In monitoring vaccinees in the pilot program, DOD found that 1,017 primary vaccinees had a take rate of 95.5 percent, and 975 revaccinees—individuals who had been vaccinated at some point in the past—had a take rate of 95.8 percent.[6] Further, DOD surveys of about 530 health care personnel vaccinated during the pilot program found that they experienced expected temporary symptoms after vaccination, such as itching, muscle aches, and headaches. DOD also reported that there was no transmission of vaccinia from a healthcare worker to a patient among the 1,992 vaccinations DOD administered.

DOD Began Full Implementation of its Smallpox Vaccination Program in January 2003

In mid-January 2003, DOD began full implementation of its smallpox vaccination program. DOD started vaccinating in stages—prioritizing its personnel according to which groups would respond first to a smallpox outbreak. Healthcare providers were vaccinated first. To do this, DOD began Stage 1a of its smallpox vaccination program, which consisted of vaccinating Smallpox Epidemiological Response Teams who would assist with epidemic control and contact tracing in an outbreak.[7] DOD's smallpox vaccination program Stage 1b consisted of vaccinating medical teams and hospital clinic teams who would care for smallpox cases. In Stage 2 of the smallpox vaccination program, DOD expanded its vaccinations to critical mission and support personnel—those who were deployed or assigned overseas, those who would be expected to deploy in a contingency, and those who support contingency forces when they deploy. (For information on the number of personnel vaccinated in each stage, see table 1.)

Table 1: Number of Personnel Vaccinated by Service and Stage as of October 8, 2003

Service	Stage 1a Smallpox epidemiological response teams	Stage 1b Medical and hospital clinic teams	Stage 2 Critical mission and support personnel	Total
Army	726	4,226	220,917	225,869
Air Force	14	3,644	81,782	85,440
Navy	20	2,053	106,476	108,549
Marines	256	0	64,577	64,833
Coast Guard[a]	669	492	16,094	17,255
Total	**1,685**	**10,415**	**489,846**	**501,946**

Source: Department of the Army.

[a]The Coast Guard is an agency within the Department of Homeland Security.

[6]Primary vaccinees were those receiving the vaccine for the first time. Revaccinees had been vaccinated at some point in the past. Because immunity to the smallpox vaccine decreases over time, DOD revaccinated personnel who had been vaccinated more than 10 years earlier.

[7]Contact tracing is the identification and tracking of individuals who may have been exposed to a person with an infectious disease.

Although the stages of the vaccination program were supposed to be separated, DOD's stages of implementation overlapped because of military deployment to Iraq in early 2003. As a result, thousands of military personnel were vaccinated in a short period of time—over 450,000 were vaccinated as of May 3, 2003—with the number of vaccinations ranging from 300 to 64,000 per week. A DOD official told us that the smallpox vaccination program is currently in a maintenance phase, with the program administering approximately 1,000 to 2,000 vaccinations per week to keep hospital staffs prepared and to prepare new forces supporting U.S. Central Command.

DOD Followed CDC Guidelines in Screening Potential Vaccinees

In administering these smallpox vaccinations, DOD told us it followed CDC's guidelines that recommend screening individuals for the contraindications that preclude smallpox vaccination.[8] According to these guidelines, DOD would not vaccinate personnel with allergies to the smallpox vaccine, those who were breast-feeding, and those who had certain cardiac conditions. In addition, DOD would not vaccinate personnel with a compromised immune system, eczema or atopic dermatitis, active skin disease such as psoriasis, or those who were pregnant—nor would DOD vaccinate personnel living with someone who had these four contraindications.[9] DOD implemented this standard because the smallpox vaccine contains a live virus that can be spread from a vaccinee to a household member. Officials from the Navy and Marines said they did not vaccinate personnel living with a child less than 1 year old.

To screen for contraindications, DOD required its personnel to fill out a form identifying contraindications that may exempt them from receiving the smallpox vaccine. Completed forms were reviewed by clinicians to resolve questions about whether specific conditions were contraindications. All services used the same screening form. DOD officials told us that contraindications resulted in exemption rates that varied by military unit, ranging from 11 to 34 percent of eligible personnel. Among service members in deployed units, living apart from their households, the exemption rates were lower—ranging from 4.9 to 7.8 percent. Skin conditions were the primary reason for being exempted from vaccination, followed by pregnancy and immune conditions.

[8]According to DOD's policy, in the event of a smallpox outbreak, all military personnel—including those with contraindications—would be vaccinated.

[9]Despite DOD's efforts to avoid vaccinating women who were pregnant, as of May 28, 2003, 85 women were vaccinated before they knew they were pregnant. These women were offered medical counseling and enrolled in a prospective registry. Similarly, as of May 28, 2003, 10 men were vaccinated before recognition that they were infected with HIV. They did not experience any adverse health reactions at the time they received the vaccine.

DOD Used Two Tracking Systems to Monitor Adverse Health Events

To monitor adverse health events following vaccination, DOD used two health information tracking systems—one to keep CDC officials apprised of adverse events following vaccinations and one for DOD officials. CDC manages, collaboratively with the Food and Drug Administration (FDA), the first system DOD used, the national VAERS.[10] VAERS serves as a national registry of individual cases of adverse events. Data submitted to this tracking system can be supplied by patients or clinicians and are completed on a VAERS form or submitted over the Internet. Although VAERS forms are typically used to record any adverse events following vaccinations, in the case of DOD's smallpox vaccinations, DOD officials said they did not expect clinicians to use VAERS forms to report the temporary symptoms expected in most smallpox vaccinees such as pustule formation, itching, or swollen lymph nodes. DOD officials told us that they decided it was more useful to record noteworthy adverse events on VAERS forms rather than more common adverse events.[11]

DOD also used its own internal information system, the DMSS, to track adverse health events following the vaccinations. DOD officials told us that military medical units were instructed to file adverse events reports simultaneously with VAERS and with the medical authority in their respective service. Each military service was then required to forward these data to DMSS. The MILVAX Agency reviewed both VAERS and DMSS data. A DOD official told us DOD used the information in DMSS to determine whether vaccinated personnel were using more healthcare services than unvaccinated personnel in order to determine whether the vaccination could be linked to reported adverse events. This information may also be used to help identify new, unusual, or rare vaccine reactions; monitor increases in known adverse reactions; as well as determine patient risk factors for particular types of adverse reactions.

By October 13, 2003, DOD recorded 184 noteworthy adverse reactions among the 501,946 vaccinations DOD administered. Of the 184 noteworthy adverse reactions, DOD reported the following:

- 62 self inoculations (virus affected other parts of body);
- 34 mild cases of generalized vaccinias (blistery body rash);
- 58 acute myopericarditis (swelling of heart tissue or sac around heart);
- 1 encephalitis (swelling of the brain);
- 1 erythema multiforme major (serious skin reaction); and
- 28 inadvertent transfers of vaccinia.

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[10]VAERS is a national vaccine safety surveillance system that encourages the reporting of any significant adverse reaction occurring after the administration of any vaccine licensed in the United States. Data reported to VAERS are reviewed by both CDC and FDA. FDA reviews adverse reactions reporting trends and assesses whether reported adverse reactions are adequately reflected in a product's labeling.

[11]DOD defined noteworthy adverse events as those that were "significant, serious, or unexpected and those that the public and clinicians should know about."

Two of the 184 noteworthy adverse reactions were serious enough to require treatments with VIG. According to DOD officials, the reported rate of adverse reactions was similar to or lower than the rates associated with previous U.S. smallpox vaccination programs, which were conducted in the 1960s. However, some experts have noted that these reported rates may not be generalizable to the population as a whole because the military population is relatively young and was carefully screened before receiving vaccinations.[12] DOD officials told us that DOD continues to monitor adverse health events for which a causal association between the vaccine and the event has not been confirmed or may be unlikely. For example, DOD is monitoring the several instances where military personnel have developed a neurologic reaction that included muscle weakness after vaccination.

DOD Facilitated Its Smallpox Vaccination Program by Ensuring the Availability of the Vaccine and by Educating Its Personnel

DOD facilitated its smallpox vaccination program by ensuring the availability of the vaccine and by educating its personnel. Specifically, DOD established practices to limit the amount of vaccine that could be wasted or contaminated. DOD also facilitated its vaccination program by educating its personnel—both those who administered the vaccine and those who received it—on the vaccination process. These actions were intended to help DOD avoid problems it encountered in administering its Anthrax Vaccine Immunization Program—such as the limited availability and general dissatisfaction among military personnel with the completeness and accuracy of the information DOD provided about the Anthrax Vaccination Program and the anthrax vaccine.[13]

DOD Took Steps to Ensure the Availability of the Smallpox Vaccine

DOD took steps to ensure the availability of the smallpox vaccine by limiting the amount of vaccine that could be wasted or contaminated. Because the smallpox vaccine may lose its potency after 90 days once the vaccine vial is opened, DOD officials told us that they took steps to minimize the number of unused doses. For example, to manage requests for the vaccine and thereby minimize the number of unused doses, each vaccination clinic was required to submit requests for the number of doses it needed to the clinic's supporting Service Vaccine Control Center.[14] Once the requests were reviewed by the centers, USAMMA authorized shipment of the smallpox vaccine.[15] Similarly, DOD officials said in order to reduce the possibility of wasting the vaccine supply, USAMMA did not ship the smallpox vaccine to small units, but brought the units to facilities where a larger number of personnel were

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[12]M. Wright and A. Fauci, "Smallpox Immunization in the 21st Century," *Journal of the American Medical Association*, vol. 289, no. 24 (2003).

[13]GAO-02-445.

[14]These centers manage and process requests for vaccines and related supplies for clinical vaccination sites. The Service Vaccine Control Centers are Naval Medical Logistics Command (NAVMEDLOGCOM), Air Force Medical Logistics Office (AFMLO), and USAMMA for both the Army and the Coast Guard.

[15]DOD acquired 1.5 million doses of the smallpox vaccine from CDC's Strategic National Stockpile.

being vaccinated. Furthermore, units with leftover doses shared their supplies with other units or with other services to reduce waste. To ensure the vaccine's potency, its temperature was monitored with a computer chip to ensure that the vaccine was maintained at the proper temperature during shipment. This monitoring process was an effort to avoid DOD's previous experience delivering the anthrax vaccine, when some vaccine was wasted because the temperature under which the vaccine was stored could not be confirmed. To ensure that the smallpox vaccine was delivered without tampering, DOC was to arrange door-to-door, escorted transportation of the vaccine from the supply depot to the pharmacies and medical depots supporting the clinics. Upon receipt, shipments of the vaccine were inspected for damage or signs of contamination.

DOD Facilitated Its Smallpox Vaccination Program with Education Efforts

According to DOD officials, DOD facilitated its vaccination program by educating those who administered the vaccine and those who received it. These efforts occurred both before and during the implementation of the program. A conference in October 2002, before the DOD smallpox vaccination program was implemented, provided training across all the services. Each service sent healthcare personnel—approximately 500 in total—to learn the vaccination procedure. The conference also provided education on vaccine history and potential adverse reactions, as well as information on the logistics of receiving and storing the vaccine. The healthcare personnel who attended were responsible for training other healthcare personnel in their units. DOD videotaped the conference and required other healthcare personnel to view various segments of the training relevant to their responsibilities in administering the smallpox vaccination program.

DOD officials told us that DOD also provided educational support to potential vaccinees. To ease concerns about receiving the smallpox vaccine, commanding officers received training materials in advance and presented information to potential vaccinees before the vaccination process began. Medical personnel attended these meetings to answer questions. In addition, questions and answers about the smallpox vaccine were posted on DOD Web sites. All of the services distributed a trifold brochure to potential vaccinees that described contraindications, the appearance of the vaccination site, the expected side effects, and instructions on how to take care of the skin area where the vaccination was administered. For additional information, the brochure listed Web site addresses and contact phone numbers. In some cases, the services required military personnel to watch a videotape describing the smallpox vaccination process. DOD organized focus groups between January and March 2003 at selected Army, Navy, Marine Corps, and Air Force facilities to identify concerns among service members, clinicians, and family members and gauge the effectiveness of educational materials. Lessons learned from these sessions were incorporated into subsequent editions of the educational material. Recommendations from these focus groups included making information available to all individuals who were going to be vaccinated or those who would come into contact with them, using layperson terms, and reinforcing the difference between the smallpox disease and the smallpox vaccination.

According to DOD officials, these education efforts were key to the successful implementation of the smallpox vaccination program. DOD officials explained that these efforts were intended to avoid some of the problems DOD encountered when it began its Anthrax Vaccine Immunization Program in March 1998. For example, a survey of Guard and Reserve pilots and aircrew in 2000 reported dissatisfaction with the completeness and accuracy of the information DOD provided on the threat posed by anthrax and on the anthrax vaccine's safety risks and possible side effects.[16]

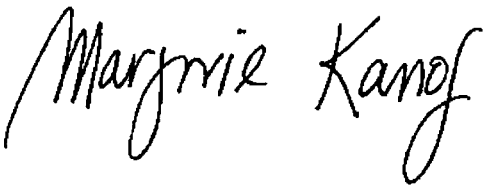
Agency Comments

In commenting on a draft of this report, DOD agreed with our findings (see enclosure). DOD also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of Defense and interested congressional committees and will make copies available to others upon request. This report will also be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staff have questions about this report, please contact me at (202) 512-7119 or Kristi Peterson at (202) 512-7951. Gloria Taylor, Louise Duhamel, and Krister Friday made key contributions to this report.

Sincerely yours,



Marjorie E. Kanof
Director, Health Care—Clinical Health Care Issues

Enclosure

[16]GAO-02-445.

Enclosure

Comments from the Department of Defense

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

REPLY TO ATTENTION OF

MCIR

14 November 2003

MEMORANDUM THRU Assistant Secretary of the Army (Manpower and Reserve Affairs)

11/14/03

John P. McLaurin III
Deputy Assistant Secretary
(Human Resources)

FOR U.S. General Accounting Office, Director, Health Care – Clinical Health Care Issues, ATTN: Ms. Marjorie E. Kanof, 441 G Street, NW, Room 5104, Washington, DC 20548

SUBJECT: Reply to U.S. General Accounting Office (GAC) Draft Report GAO-04-215R, *SMALLPOX VACCINATION: Review of the Implementation of the Military Program*

1. This is the Department of Defense (DoD) response to the GAO draft report GAO-04-215R, "*Smallpox Vaccination: Review of the Implementation of the Military Program*," dated November 4, 2003. We appreciate the opportunity to comment on your report.

2. We concur with your report and its findings as written.

3. Our point of contact is COL John Grabenstein, Deputy Director for Clinical Operations, Military Vaccine Agency, (703) 681-5059. COL Grabenstein served as the primary action officer on behalf of the DoD for this GAO review.

FOR THE SURGEON GENERAL:

Encl

KENNETH L. FARMER, JR., M.D.
Major General
Deputy Surgeon General

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(290275)

U.S. Army Center for Health Promotion and Preventive Medicine

USCHPPM

FINAL REPORT
PROJECT NO. 33-DA-5773-03
RESULTS OF THE DOD SMALLPOX VACCINATION PROGRAM
FOCUS GROUPS EFFORT
JANUARY-MARCH 2003

Readiness Thru Health

U.S. Army Center for Health Promotion and Preventive Medicine

The lineage of the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) can be traced back over 50 years. This organization began as the U.S. Army Industrial Hygiene Laboratory, established during the industrial buildup for World War II, under the direct supervision of the Army Surgeon General. Its original location was at the Johns Hopkins School of Hygiene and Public Health. Its mission was to conduct occupational health surveys and investigations within the Department of Defense's (DOD's) industrial production base. It was staffed with three personnel and had a limited annual operating budget of three thousand dollars.

Most recently, it became internationally known as the U.S. Army Environmental Hygiene Agency (AEHA). Its mission expanded to support worldwide preventive medicine programs of the Army, DOD, and other Federal agencies as directed by the Army Medical Command or the Office of The Surgeon General, through consultations, support services, investigations, on-site visits, and training.

On 1 August 1994, AEHA was redesignated the U.S. Army Center for Health Promotion and Preventive Medicine with a provisional status and a commanding general officer. On 1 October 1995, the nonprovisional status was approved with a mission of providing preventive medicine and health promotion leadership, direction, and services for America's Army.

The organization's quest has always been one of excellence and the provision of quality service. Today, its goal is to be an established world-class center of excellence for achieving and maintaining a fit, healthy, and ready force. To achieve that end, the CHPPM holds firmly to its values which are steeped in rich military heritage:

★ *Integrity is the foundation*
★ *Excellence is the standard*
★ *Customer satisfaction is the focus*
★ *Its people are the most valued resource*
★ *Continuous quality improvement is the pathway*

This organization stands on the threshold of even greater challenges and responsibilities. It has been reorganized and reengineered to support the Army of the future. The CHPPM now has three direct support activities located in Fort Meade, Maryland; Fort McPherson, Georgia; and Fitzsimons Army Medical Center, Aurora, Colorado; to provide responsive regional health promotion and preventive medicine support across the U.S. There are also two CHPPM overseas commands in Landstuhl, Germany and Camp Zama, Japan who contribute to the success of CHPPM's increasing global mission. As CHPPM moves into the 21st Century, new programs relating to fitness, health promotion, wellness, and disease surveillance are being added. As always, CHPPM stands firm in its commitment to Army readiness. It is an organization proud of its fine history, yet equally excited about its challenging future.

EXECUTIVE SUMMARY
FINAL REPORT
PROJECT NO. 33-DA-5773-03
RESULTS OF THE DOD SMALLPOX VACCINATION PROGRAM
FOCUS GROUPS EFFORT
JANUARY-MARCH 2003

1. PURPOSE. This report identifies and provides recommendations for addressing the concerns and information needs of various service members, their families, and health care providers relative to the Department of Defense (DOD) Smallpox Vaccination Program. At the request of the Military Vaccine (MILVAX) Agency at the Office of The Surgeon General, the U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM) conducted the this effort over a 3-month period using a broad range of participants from all the services (Army, Air Force and Navy, including the Marine Corps). USACHPPM immediately communicated the results from each focus group to MILVAX. In turn, MILVAX was able to quickly update information provided through its website, brochures, and direct interaction with service members.

2. CONCLUSIONS.

a. A proactive information campaign is necessary and is working. MILVAX risk communication strategies developed before the start of the DOD Smallpox Vaccination Program were confirmed as sound, and the focus groups provided further opportunity to fine-tune information and communication.

b. The target audience is broader than just service members.

c. Pre-vaccination briefings scheduled in advance of administering the vaccination allow service members and their families time to understand and discuss the information provided and to conduct additional research if necessary.

d. Service members and their families rely on DOD health care information sources **and** external, civilian sources of information.

e. The real-time feedback to MILVAX of the results of the focus groups produced lessons learned, recommendations, and best practices responsive to the expressed concerns and suggestions of service members, their families, and health care providers.

3. RECOMMENDATIONS.

a. Ensure information is relevant and tailored to the diverse audience groups of service members, family members, health care providers, civilians, and coworkers.

b. Improve pre-vaccination briefings and vaccination screening by identifying and using health care workers with good risk communication skills, emphasizing and repeating key vaccination site care information, and reinforcing the difference between smallpox disease and the smallpox vaccine.

c. Distribute standardized education materials to all health care providers to help ensure a common message is delivered.

d. Provide guidance and encouragement in the form of a generic risk communication strategy to health care facilities to assist in developing and implementing local risk communication plans. Place the generic strategy on the MILVAX website with other planning documents with instructions to modify to meet local needs.

e. Ensure publicity is designed to stress the fact that the DOD Smallpox Vaccination Program is benefiting from lessons learned from the anthrax vaccination program and that new information is being continually developed and disseminated.

Final Report, Project No. 33-DA-5773-03, Results of the DOD Smallpox Vaccination Program Focus Groups Effort, January-March 2003

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MCHB-TS-RHR

FINAL REPORT
PROJECT NO. 33-DA-5773-03
RESULTS OF THE DOD SMALLPOX VACCINATION PROGRAM
FOCUS GROUPS EFFORT
JANUARY-MARCH 2003

1. REFERENCES. Appendix A contains a listing of references.

2. AUTHORITY.

a. Electronic mail message between COL John Grabenstein, Military Vaccine (MILVAX) Agency, Office of The Surgeon General, and Ms. Marilyn Null, Program Manager, Health Risk Communication, U.S. Army Center for Health Promotion and Preventive Medicine (USACHPPM); November 2002; subject: Proposed Focus Groups Effort Relative to the DOD Smallpox Vaccination Program.

b. In December 2002, MILVAX approved the Smallpox Risk Communication Strategy Development Focus Group Plan. See appendix B.

3. PURPOSE. This effort identifies and provides recommendations for addressing the concerns and information needs of various service members, their families, and health care providers relative to the Department of Defense (DOD) Smallpox Vaccination Program. At the request of MILVAX, USACHPPM conducted the focus groups over a 3-month period using a broad range of participants from all the services (Army, Air Force and Navy, including the Marine Corps). USACHPPM immediately communicated the results from each focus group to MILVAX. In turn, MILVAX was able to quickly update information provided through its website, brochures, and direct interaction with service members.

4. BACKGROUND.

a. Vaccination against disease and threats of biological weapon attacks are crucial to Force Health Protection. To ensure that the DOD Smallpox Vaccination Program proceeds successfully, the military needs to effectively communicate accurate and timely information about the smallpox vaccine to its troops, health care providers, family members, and other members of the public.

(1) To help achieve that goal, MILVAX requested that the Health Risk Communication Program at USACHPPM conduct focus groups comprised of service personnel, their families, and health care providers to gain a better understanding of their concerns and information needs regarding the DOD Smallpox Vaccination Program. Many of the findings from this effort are consistent with the guidance provided in the DOD Smallpox Vaccination Lessons Learned document that is currently posted on the MILVAX website (http://www.smallpox.army.mil).

(2) This report consists of findings and recommendations that can be used to develop and implement a comprehensive risk communication strategy for effectively addressing the issues raised by these stakeholders.

b. To ensure consistent and comparable results from the focus groups at multiple locations and among all services, USACHPPM developed a focus group plan, and MILVAX approved the plan in December 2002. (See appendix B.) The focus group process articulated in the plan called for the formation of a traditional focus group followed by a question-and-answer session with a smallpox vaccination subject matter expert. The interactive dialogues between the focus group participants and the subject matter experts had two positive outcomes: increasing the knowledge of the participants and strengthening the information gathered with additional insight relative to participant concerns and information needs.

c. Beginning in early January and concluding in late March 2003, USACHPPM conducted 14 different focus groups consisting of a cross section of military services with 143 service members, family members, and health care providers. Although some focus group participants had been vaccinated, most had not. Table 1 summarizes information about the focus groups.

Table 1. Details on Focus Groups Conducted

Location and Dates of Focus Group Sessions	*Specific Focus Groups*	*Number of Participants*
Wilford Hall Medical Center, Lackland Air Force Base, Texas 7 January 2003	Air Force health care providers	15
Kirk Army Health Clinic, Aberdeen Proving Ground, Maryland 15 January 2003	Army health care providers	14
Madigan Army Medical Center Fort Lewis, Washington 11 February 2003	• Army health care providers • Soldiers • Family members	4 27 3
Naval Amphibious Base Little Creek Virginia Beach, Virginia 25 March 2003	Family members and health care providers	13
Naval Medical Center Portsmouth 26 March 2003	Immunization clinic staff, other health care providers, and Navy personnel from the Regional Support Group	10
Naval Weapons Station Yorktown Yorktown, Virginia 26 March 2003	Marine Corps Unit	11
Norfolk Naval Base Norfolk, Virginia 27 March 2003	Naval aviators	12
Naval Amphibious Base Little Creek Virginia Beach, Virginia 27 March 2003	Navy special operations	3
Naval Amphibious Base Little Creek Virginia Beach, Virginia 27 March 2003	• Navy shipboard personnel and explosive ordnance disposal divers • Navy shipboard personnel	7 5
Naval Medical Center Portsmouth 28 March 2003	Navy and civilian health care providers	13
Naval Medical Center Portsmouth 28 March 2003	Navy and civilian health care providers	6

5. FINDINGS AND OBSERVATIONS.

a. General Concerns and Observations.

(1) Those scheduled to receive the vaccine had significantly more information than those who were not yet scheduled to receive the vaccine.

(2) There was some confusion about the difference between smallpox disease and the smallpox vaccine, especially among younger, junior enlisted participants. Some participants believed that people can catch the disease from taking the vaccine or from someone who has been vaccinated. Overcoming this confusion took some time. We observed several instances in which the subject matter expert explained the difference between vaccine and smallpox; however, subsequent questions from participants made it clear that the two were still interwoven in the minds of the participants.

(3) In a number of the focus groups, participants questioned whether there are different strains of smallpox and, if so, whether the current vaccine protects people against the different strains.

(4) There was confusion and concern about the vaccine itself. Some participants had heard there are "old" and "new" vaccines and wanted to know whether there is a difference between the two, whether the contractor making the new vaccine is trustworthy, whether the "old" and "new" vaccines have been or will be tested and have Food and Drug Administration (FDA) approval, and whether there will be enough vaccine. There were some questions regarding whether the vaccine is made from the smallpox virus.

(5) Participants had questions about people who had been previously vaccinated, such as—

(a) Do they need to be vaccinated again?

(b) How long are the vaccinations effective?

(c) Why does a person need more "pricks" the second time he or she is vaccinated?

(6) Some participants asked questions about who will be vaccinated and whether the vaccine will be available for family members.

(7) Participants had concerns regarding potential risk to children, pregnant women, and other vulnerable individuals who come in contact with people who have been vaccinated.

(8) Participants had knowledge of and concern about recent deaths of civilian health care workers with heart problems who had received the vaccine.

(9) Participants expressed concerns regarding a range of risks related to vaccination site care, for example, sharing showers and co-mingling laundry.

(10) Some participants expressed concerns about scarring at the vaccination site.

(11) Some participants voiced concerns about pets.

b. Service Member Concerns and Observations.

(1) Service members (who were not yet in the vaccination program and who had not received pre-vaccination briefings) lacked basic information on smallpox and the smallpox vaccine (see para 5-a), with some relying on the media for information and others receiving information for the first time during the focus group session and the education session immediately following.

(2) Some participants were concerned about whether the smallpox virus could penetrate their protective gear, whether it could be spread through the water supply, and whether family pets could pass it on.

(3) Service members wanted to know the ratio of the number of service members who have had adverse effects from the vaccine to the total number who have been vaccinated.

(4) Some participants were confused about whether service members who were vaccinated would be required to lodge away from their families. Service members were especially concerned about spending time away from their families immediately before deployment. Several participants suggested that vaccinations be given after deployment.

(5) In one area, local gyms had posted signs saying that those recently vaccinated could not use the gyms until medically cleared, which raised general concerns about the safety of the vaccinations and questions about working out while the vaccination site heals.

c. Health Care Provider Concerns and Observations.

(1) Health care providers at all levels and in all areas were receiving a significant number of questions about smallpox and the vaccination program. In some places, all providers had been fully briefed on the issues and were able to respond to questions and allay concerns. Other providers had limited knowledge, felt ill equipped to answer patients' questions, and, in some cases, had some of the same misconceptions about the vaccine as their patients. Focus group

participants recommended that all providers receive training and information, even if they are not personally involved with the DOD Smallpox Vaccination Program.

(2) Health care providers reported that constant repetition of key information is a crucial part of the pre-vaccination screening process. They provided examples of service members who had heard the briefing, completed the screening questionnaire, spoken with a provider to review the information on the screening questionnaire, and still revealed for the first time that they had a possible contraindication just as they were about to be vaccinated. In some cases, providers felt that the individual service member might not have wanted to appear "weak," so did not share relevant information until the last minute. Private pre-vaccination screening might result in more accurate responses to contraindication questions and be a better forum for asking personal questions.

(3) Contract health care workers who were being asked to voluntarily take the vaccination to serve as first responders raised the issue of time off from work if they had an adverse reaction to the vaccination. Specifically, in the event a worker had to miss time from work—

(a) Would the employee have to use accrued annual leave and/or sick leave, or would the military pay the contract employee for the time off?

(b) Would worker time off cause staffing problems for the hospital?

(4) Several health care providers noted that if people are really concerned about getting vaccinated, they can figure out how to avoid it through the screening process.

(5) Some health care providers discussed the challenge of being accused of a cover-up if something should go wrong and advocated making all information available so that there would be no perception that the military was hiding something.

d. Family Member Concerns and Observations.

(1) Service members should not be relied on exclusively to get information to their families. Participants recommended alternative communication strategies and tools for informing family members.

(2) Family members would prefer to get information directly through a variety of sources including electronic mail, family resource groups, family service centers, command spouse ombudsmen, installation newsletters, TRICARE publications, newspapers, flyers in high-traffic areas, and health care providers. Focus group participants emphasized that more than one method of communication should be used. Family members recommended general outreach

using these vehicles that are available to anyone who has concerns or wants to better understand the DOD Smallpox Vaccination Program.

(3) Family members requested they be included in the pre-vaccination briefing of the service member so that the entire family unit gets the same information at the same time.

(4) Family members were concerned about whether the smallpox vaccination interacts with booster shots given to children.

e. Perceptions of Threat.

(1) Some health care providers reported that many vaccination candidates are not overly concerned about the threat of exposure to smallpox and, therefore, do not really understand the need for the vaccination. This was true even of those not concerned about being inoculated.

(2) Other providers reported having requests for children and family members to be inoculated.

(3) In general, most participants felt the threat was greater outside the continental United States (OCONUS) than in the continental United States (CONUS). However, some Special Operations participants felt the threat of the disease was greater CONUS than OCONUS.

(4) Some participants wanted to know why smallpox vaccinations are being given now and not as part of the standard vaccination series given to service members. They wondered whether the threat is greater now than it was previously.

f. Information/Briefings.

(1) In general, it was determined that it is beneficial to provide information prior to vaccination. Providing enough time for independent research and discussion with family members is especially helpful. On the other hand, too much time could allow people to forget important information. The participants recommended that briefings be given anywhere from a few days to one month before vaccination.

(2) In pre-vaccination briefings, question-and-answer (Q&A) sessions, and direct interactions, information tailored to the audience is better understood. In general, more mature, experienced officers and senior noncommissioned officers seemed to grasp and understand information on the vaccine and disease more readily than younger, less-experienced service members.

(3) Interactive information exchange such as commander's calls or town hall meetings—where people have opportunities to ask questions and get answers directly—were identified by participants as the most valuable way for getting information to people, including combinations of service members and their families. People found print and web-based sources of information most useful when coupled with interactive sessions. Providers, service members, and family members all advocated use of interactive sessions to establish credibility and address people's concerns.

(4) Feedback on the MILVAX trifold brochure, What You Need to Know About Smallpox Vaccine (reference 1), was mostly positive, although some providers said that its usefulness was limited and that it was often thrown away without being read. One service member called it "propaganda." Most respondents, however, felt that it was an important tool to have as a take-away to be used in conjunction with a briefing or other interactive exchange or if someone requested information on smallpox or the vaccine. There was mixed feedback on the pictures: some participants felt the pictures got people's attention; others felt the pictures could unnecessarily alarm people. Some participants noted that the brochure showed a picture of what could happen if service members did not take proper care of the vaccination site but did not show the effects of smallpox disease.

(5) The new MILVAX brochures, Somebody in Your Household Just Got Vaccinated Against Smallpox: What Should You Do? (reference 2) and After You Get the Smallpox Vaccine: Protecting Pets and Other Animals (reference 3), were well received. Participants felt that these brochures addressed some of the most important questions. The questions people asked continued to focus on the personal impacts of getting the vaccine—

(a) What about laundry?

(b) Can I go to the gym to work out?

(c) Can I autoinoculate myself from my sheets or from sweating?

(6) Participants raised several other questions—

(a) Does the mortality rate from the disease differ among different races or ethnic groups?

(b) Are there different side effects from the vaccine based on age and gender?

(c) Why is the vaccine being given now? Is the threat greater than it has been portrayed?

(d) If a vaccinee accidentally transfers vaccinia to a person, is that person then protected from smallpox?

(7) Results from the focus groups indicate that the communication strategies being used for providers and service members currently scheduled to be vaccinated are effective; however, other stakeholder groups are not getting adequate information.

(a) Co-workers have raised safety concerns about being exposed to vaccinated individuals in their work environment.

(b) Family members have numerous questions and concerns and would like to receive information directly. Relying on service members to inform family members about smallpox and the vaccine is ineffective.

(c) Service members not yet scheduled to receive the vaccine are unsure under what priority they will be scheduled for vaccinations. More importantly, service members who have not yet received the smallpox briefings and information have a number of common misconceptions about smallpox and the vaccine.

(d) The military medical system relies in part on contract personnel. The military information network may not include contract personnel and, therefore, information may not adequately reach contract health care providers.

(8) All agreed that there is a great deal more information available about the smallpox vaccine than there was about the anthrax vaccine when that vaccination program was first implemented.

g. Sources of Information.

(1) For health care providers especially, the Centers for Disease Control and Prevention (CDC) (reference 4) and MILVAX (reference 5) web sites were almost universally considered good sources of information. Health care providers have taken advantage of the training and communication resources that are available on both sites and highly recommend them. Other web sites mentioned were Johns Hopkins University (reference 6), the U.S. Department of Health & Human Services (DHHS) (reference 7), and the Maryland Department of Health and Mental Hygiene (DHMH) (reference 8). Some health care providers noted the importance of directing people to legitimate sources of information to counterbalance the misinformation that is also available. Some health care providers said they did not always have the time to work their way through all the information on the web sites. One health care provider indicated it took from 45 minutes to 1 hour to get through it all.

(2) The CDC proactively communicates information to nurses and some other licensed medical professionals; however, some specialties do not receive CDC information.

(3) Many service and family members indicated the CDC and other civilian web sites, such as WebMD® (reference 9), as alternative sources of credible information.

(4) Some participants do not trust the military or the Federal government as a source of information. Some mentioned issues related to Gulf War Illness and the anthrax vaccine. However, most participants expressed trust and confidence in unit medical personnel (physicians or corpsman/medics assigned directly to units), indicating that the more familiar the source and the more the source shares similar risks (the fact that these medical personnel have been or will also be vaccinated), the more the source can be trusted. The value of military physicians and other health care providers with good risk communication skills in interacting with service members and their families was demonstrated. Service members and their families said that their personal health care providers are the most commonly used and trusted sources of information about smallpox and other health issues.

(5) Cable News Network (CNN®) (reference 10) is another common source of information; however, providers were concerned that the media tend to sensationalize information about smallpox and needlessly heighten the level of concern.

(6) Health care providers appreciated being able to refer people to civilian sources to reinforce the messages and credibility of the information that is provided by the military.

6. CONCLUSIONS.

a. A proactive information campaign is necessary and is working. MILVAX risk communication strategies developed before the start of the DOD Smallpox Vaccination Program were confirmed as sound, and the focus groups provided further opportunity to fine-tune information and communication.

b. The target audience is broader than just service members.

c. Pre-vaccination briefings scheduled in advance of administering the vaccination allow service members and their families time to understand and discuss the information provided and to conduct additional research if necessary.

® WebMD is a registered trademark of WebMD Corporation, Elmwood, New Jersey.
® CNN, an AOL Time Warner Company, Atlanta, Georgia.

d. Service members and their families rely on DOD health care information sources **and** external, civilian sources of information.

e. The real-time feedback to MILVAX of the results of the focus groups produced lessons learned, recommendations, and best practices responsive to the expressed concerns and suggestions of service members, their families, and health care providers.

7. RECOMMENDATIONS. USACHPPM formulated recommendations based on suggestions made directly by focus group participants and on an analysis of the comments made during the focus group sessions and Q&A sessions.

a. Broaden the targeted audience and message for communication about the DOD Smallpox Vaccination Program.

(1) Information should be made available to all people who are to be vaccinated or who will come into contact with people vaccinated, i.e., service members, family members, medical personnel, and co-workers. Information, communication channels and tools, and opportunities to ask questions and receive answers need to be designed with these different audiences in mind.

(2) The value of effective communication and outreach to family members should be emphasized to commanders by providing guidance and suggestions on approaches and activities, e.g., town hall meetings, family support group meetings, flyers and brochures in high-traffic areas, etc.

(3) Family members require communication strategies specifically designed to reach them and should not have to rely on service members to communicate what they need to know.

(4) Information should be provided earlier about vaccination priority, the smallpox threat, and the vaccine to help increase knowledge and prepare service members for the vaccination process.

(5) Information should emphasize the difference between smallpox disease and the smallpox vaccination.

b. Enhance the effectiveness of pre-vaccination briefings.

(1) When conducting pre-vaccination briefings and vaccination screening, health care providers serving as spokespersons should—

(a) De-emphasize medical jargon and put information in layperson terms.

(b) Emphasize their personal concern for the service members and their families.

(c) Tailor the level of information and the detail provided to the specific audience.

(d) Communicate that the screening process is designed to eliminate those at risk and that the screening criteria are very conservative (e.g., the recent addition of screening questions related to heart conditions).

(e) Discuss the physician or health care provider's own personal experience with the vaccine (if relevant), including expected vaccine reactions and what precautions the spokesperson took around his or her family.

(f) Present information about the risk of smallpox disease as compared to that of taking the smallpox vaccine.

(2) As a best practice, health care providers should continually emphasize and repeat the same information throughout the vaccination process. This is especially important in educating people about vaccination site care and as part of the screening process. Health care providers reported that this constant repetition is a crucial part of the screening process. Some reported "quizzing" service members to ensure they understood the briefing, which should be encouraged as a best practice.

(3) The briefings should reinforce the difference between smallpox disease and the smallpox vaccination.

c. Encourage pre-vaccination briefings in advance of actual vaccinations. Based on feedback from participants, people should receive pre-vaccination briefings 1 to 2 weeks before vaccination so they have plenty of time to ask questions and share information with family members.

d. Identify and use health care workers with good risk communication skills. Health care providers, especially military physicians, with basic and effective risk communication skills are invaluable. A cadre of military physicians and other health care providers should be selected to receive basic risk communication spokesperson training (similar to that offered by the MILVAX spokesperson training courses). These physicians and health care providers should be made available to address and answer questions from service members and their families at commander's calls, town hall meetings, and family support groups.

e. Adopt communication tools best suited to reaching the different target audiences.

(1) Military treatment facilities (MTFs) should be encouraged to develop their own risk communication strategy to address local concerns and issues. MILVAX should develop a generic template, with guidance on how to tailor it to local needs.

(2) Multiple information channels, such as those suggested in the focus groups, should be developed and used to inform family members (for example, electronic mail, family resource groups, family service centers, command spouse ombudsman, installation newsletters, TRICARE publications, newspapers, and flyers in high-traffic areas like the post exchange).

(3) Because existing communication tools are focused on people who will be vaccinated, these tools do not adequately address audiences such as family members and co-workers who may be interacting with vaccinated people. Information should be added to existing communications tools, and others should be developed (in addition to the MILVAX brochures concerning household contacts and pets) to address the concerns of people living with those who have been vaccinated.

(4) Commonly heard concerns should continue to be addressed in the Q&A section on the MILVAX website and updated based on questions posed to MILVAX's information line and the DOD Vaccine Healthcare Centers (reference 11).

f. Standardize and distribute education materials to all health care providers (not just those directly involved with the vaccination program). All health care providers, including contract personnel, need to be educated so that they can answer questions and correct misconceptions. Primary care providers need to be prepared to answer questions because they are often viewed as a trustworthy and accessible source of information about smallpox and other health-related concerns. Immunization clinic workers need to have consistent information available to respond to questions during screening and vaccinations. Implementing this recommendation may require mandatory briefings to ensure implementation and priority.

g. Continue to provide more information and education about the reality of the smallpox threat both directly to health care providers and to service personnel. More information is needed about the threat, but the message should not be sensationalized. Reports from locations where vaccinations are being given indicate that the process is working, and few adverse reactions have been reported. This message should continue to be delivered with information about the threat to create a balanced message.

h. Provide tips on how the military can establish and maintain credibility in its communications about the DOD Smallpox Vaccination Program.

(1) Medical providers do this by referring patients to the CDC and other quality civilian sources of information along with the MILVAX trifold brochure and other MILVAX resources.

Civilian sources reinforce the message and credibility of the information provided by the military. Note: The CDC also has information in Spanish. MILVAX may want to consider providing its brochures in Spanish; if this is not feasible, then people should be referred to the CDC Spanish language information source.

(2) Opportunities for people to ask questions should continue to be provided. Q&A sessions during the briefings do more than provide information; they also build relationships and demonstrate openness and honesty.

i. Provide guidance and encouragement to health care facilities to develop and implement local risk communication plans. Local plans should be sensitive to site-specific concerns, needs, and resources and, therefore, most effective in addressing the issues raised by service members, family members, and co-workers who have not yet received the vaccination. The tools provided by MILVAX and the CDC will have the greatest impact when used as part of a local initiative that has considered local stakeholders' needs, taken advantage of available channels of communication, and identified talented risk communicators. The Health Risk Communication Program at USACHPPM, the Navy Environmental Health Center (NEHC), and the Air Force Institute for Operational Health (AFIOH) are available to help put together guidance and work with local facilities if needed.

j. State that the DOD Smallpox Vaccination Program is using lessons learned from the anthrax vaccine program, and, consequently, the DOD has changed the way it communicates about anthrax and smallpox. Following are specific examples of lessons learned from the focus groups:

(1) Briefing candidates several days prior to vaccination is important to allow concerns to emerge and be addressed, including those of family members.

(2) The smallpox program is providing much more information than did the anthrax program, and the information is readily available to both service members and health care providers.

k. Continue to publicize what is working well, and provide status information on the DOD Smallpox Vaccination Program.

(1) A status report can be distributed within the military and then disseminated to the media. The existing information available on the MILVAX website (Adverse Event Information/Vaccine Adverse Event Reporting System (VAERS) Information and Reporting/Safety Summary to Date) (reference 12) is a good starting place, but it is targeted at health care providers. MILVAX should document the separate installation experiences and provide an overall assessment of the preliminary success of the DOD Smallpox Vaccination

Program to a broad audience—service members and their families, health care providers, the public, and the media. Key elements that could be covered in such a report include the following:

(a) The process—what is being done to vaccinate troops and health care providers?

(b) How is the process going? How is the military doing?

(c) What has been done so far? Provide accurate data regarding the vaccinations that have already been given. (How many inoculations have been given? How many of those vaccinated have had side effects, and what specific side effects have been seen? What percentage of those vaccinated have had side effects?)

(d) Define future actions. Continue to give status reports and share lessons learned.

(e) Publicize the MILVAX toll-free number and website.

(2) Media interviews of MILVAX leadership have helped communicate the facts about the DOD Smallpox Vaccination Program. Opportunities to proactively inform the media and other interested audiences should continue to be sought and used.

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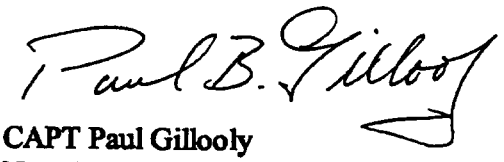
Final Report, Project No. 33-DA-5773-03, Results of the DOD Smallpox Vaccination Program Focus Groups Effort, January-March 2003

REVIEWED:



CAPT Paul Gillooly
Navy Environmental Health Center

Final Report, Project No. 33-DA-5773-03, Results of the DOD Smallpox Vaccination Program Focus Groups Effort, January-March 2003

REVIEWED:

Kenneth L. Cox

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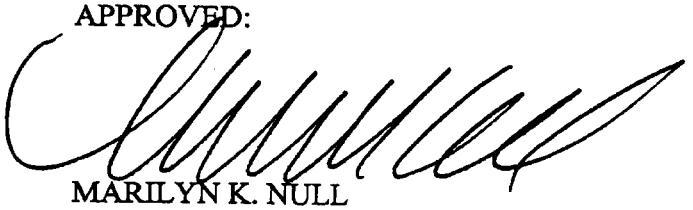
Air Force Institute for Operational Health

Final Report, Project No. 33-DA-5773-03, Results of the DOD Smallpox Vaccination Program Focus Groups Effort, January-March 2003

APPROVED:



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APPENDIX A

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APPENDIX B

SMALLPOX RISK COMMUNICATION STRATEGY DEVELOPMENT FOCUS GROUP PLAN DECEMBER 2002

Focus groups are the first step in Phase I of the Smallpox Risk Communication Strategy Development Proposed Action Plan. Phase I includes focus groups, Q&A sessions, and opportunities for risk communication training for those involved in administering the vaccine. Phase II will use the information gathered in Phase I to develop and implement a comprehensive risk communication strategy for the smallpox vaccination program. This is a tri-service effort involving the Army, Air Force, and Navy (including Marine Corps).

Mission

To determine what concerns service members, their families, and health care staff may have regarding the smallpox vaccine.

Client

MILVAX (Military Vaccine Agency, Office of The Surgeon General, U.S. Army Medical Command)

Objective

The focus groups will gather feedback directly from service members, their families, and health care providers about their personal concerns and interests in the military smallpox vaccination program. This data will be used to develop a risk communication strategy for the smallpox vaccination program that helps prevent issues similar to those faced during the anthrax vaccinations. The goal is to complete the focus group process and develop a risk communication strategy before smallpox vaccinations begin for the majority of service members.

Focus Group Participants

Commander support is required for the success of the focus groups. This effort will need MILVAX, CHPPM, AFIERA, and NEHC assistance in identifying the appropriate locations and getting Command support at those locations. This must be done quickly so the focus groups can be conducted during the first week in January 2003.

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Focus groups consist of people who share certain characteristics – in this case, military service, likely deployment, and job specialties (e.g., health care providers). Ideally, a focus group aims for diversity within a specified category in order to gain an understanding of the entire spectrum of that group's perspective, attitude, level of experience, etc.

Participants will include, in separate groups:

- Service members (excluding health care staff)
- Families of service members
- Health care staff

Note: The objective of using the focus group approach to gather information important in developing an effective risk communication strategy requires an open and honest discussion of issues. To ensure that participants are comfortable speaking candidly about their concerns, it is strongly suggested that senior commanders not be included with their subordinate personnel. For the same reason, service members and their families should be in separate focus groups (made up entirely of either service members or family members).

Health care staff will be represented in separate focus groups because their questions, concerns, and issues are likely to be different from those of the non-health care service members and families. Enlisted service members who are medics will participate in focus groups with other health care staff.

Each service has been contacted to garner support and help in recruiting focus group participants without impacting unit mission or deployment.

The focus groups will consist of people who are unvaccinated but are scheduled for vaccinations and those who are unvaccinated and are not currently scheduled for vaccinations. Since the effort is getting underway after some vaccinations have started, doing a focus group with those recently vaccinated is also recommended.

Focus Group Process

Focus groups provide insights into the attitudes, opinions and perceptions of a target group. They are especially useful in exploring underlying issues and revealing complex behavior or motivation. Results come from facilitating a non-threatening, confidential discussion guided by open-ended questions. Responses are compiled and analyzed and can be used to inform the development of strategy and actions.

1. Ideally, there will be at least two focus groups per service for a total of six focus groups. Each focus group will have a maximum of 25 participants and run for approximately one hour.
2. These focus groups will likely take place concurrently over a two-to-three day period in the first week of January 2003.
3. Each focus group will have one facilitator and one recorder, which will be provided by CHPPM. The facilitator will guide the group through an informal discussion using open-ended questions designed to draw out underlying thoughts, feelings, and attitudes about the smallpox vaccination. Having a separate recorder enables the facilitator to remain focused on the discussion, draw out participants, and maintain a less formal setting, which generates more free and open conversation. To create an environment where all participants are likely to share information, at least one of these individuals will be non-military.
4. All responses in the focus group will be confidential and non-attributable – participants will be told this at the beginning of the discussion and will be included in the written ground rules for each focus group. The recorder will document what people in the focus group say (but not who says it).
5. Focus groups will be followed by a Q&A session with subject matter experts from the DoD and potentially the Centers for Disease Control and Prevention (CDC). The Q&A session will run for one-half hour to one hour, depending on the number of participant questions. This will serve to provide information directly to participants and give them the opportunity to ask questions directly of the experts.
6. Risk communication training will be available to health care staff and others involved in administering the smallpox vaccine. This training will help prepare health care workers to communicate effectively with concerned patients during the vaccination process using information learned in the focus groups. If the training is desired, CHPPM will work with each location to determine the appropriate length of the session (2 hours, 4 hours, 1 day, etc.)

Focus Group Questions

The following questions are designed to guide the discussion during focus group sessions. Discussion is intended to be free flowing, and not all questions may be asked.

Service Member and Family Focus Groups

What have you heard about the smallpox vaccine? What do you know about it?

How likely do you think you are to be exposed to smallpox if you are deployed? How concerned are you about being exposed to smallpox if deployed?

How likely do you think you are to be exposed to smallpox if you remain in the United States? How concerned are you about being exposed to smallpox if in the U.S.?

What information sources do you rely on for information about smallpox vaccination program?
- Military sources
- Civilian sources (informal and formal)

(chain of command, mayoral program, peers, health care providers, media, journals, etc.)

What kinds of concerns do you have about the smallpox vaccine?
- for yourself
- for your family
- if you get the vaccine
- if you don't get the vaccine
- if your family gets the vaccine
- if your family doesn't get the vaccine

Who would you trust for information about the smallpox vaccine (and its impacts)?

Where do you go to raise concerns about health issues? Where else? Where do you wish you could go? Where does your family go for info? Where would you like your family to be able to get information?

What priority has DoD placed on the smallpox vaccination program? What do you base this assessment on?

When is the best time to inform the service personnel about the need to receive a smallpox vaccine?

What key information about the smallpox vaccine needs to be communicated to all personnel? To families?

Questions for Health Care Staff.

Do you have concerns about the smallpox vaccine?

What kinds of concerns have you heard from patients about the smallpox vaccine in particular?

What do you think are the widely held perceptions that you believe are misconceptions about the smallpox vaccine? What is the basis for each perception? Is there some truth to it? How has (or how will) the perception, whether valid or not, affected you in your work?

What key information about the smallpox vaccine needs to be communicated to all personnel? To families?

Who would you like to get that information from?

What has been done to encourage understanding about the smallpox vaccine? How successful were these efforts? What more could be done?

Do you feel you have the information you need about how the smallpox vaccination program will work and impacts of the vaccine?

How prepared are military health care providers to communicate about the smallpox vaccine and its impacts?

Are you comfortable administering the smallpox vaccine?

What opportunities do you have for providing information to service members about the smallpox vaccine?

What challenges do the Armed Services face in communicating about the smallpox vaccination program? What needs to be improved for communicating about the smallpox vaccination program?

What is the best way to communicate to service members about the need for and impacts of the smallpox vaccine? Family members?

What lessons learned are you aware of from your experience related to vaccination issues/programs? From ongoing studies related to vaccination programs?

Report

Each facilitator will summarize the results of their respective focus group discussions and provide the information to a single POC to consolidate into a final report within 10 business days of the last focus group. CHPPM's contractor will provide a draft of the report to CHPPM for review within eight days of the last focus group. CHPPM will forward the first draft of the report to AFIERA and NEHC for their review. CHPPM's contractor will incorporate CHPPM, AFIERA, and NEHC comments, and return the final report to CHPPM within one week of receiving comments for final delivery to MILVAX.

The report will document focus group input, analyze and categorize comments, and identify common issues and concerns. CHPPM will use this information to initiate development of an

effective risk communication strategy that addresses the explicit and underlying issues and concerns raised.