

## **A CASE STUDY IN ASSESSMENT AND ASSURANCE**

### **“Shifting Gears: From Everyday Provision of Public Health Services to Mass Vaccinations.**

*How Does Middletown Prepare and Implement a  
Controversial Health Program to a Larger Segment of the Population?”*

The Mid-America Regional Public Health Leadership Institute  
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**Abstract:**

Health departments across the US now have an even greater responsibility and challenge to provide health services in their communities. On December 14, 2002, the President announced the implementation of a national Pre-Event Smallpox Initiative. The federal government released little information regarding the phases for the plan beyond Phase I, but did indicate that a Phase II would include all hospital workers and first responders (police, fire and paramedics) with nationwide totals reaching as many as millions. This initiative will stretch the capacity of all health departments – large and small. The Illinois Department of Public Health (IDPH) required each county health department to submit a plan for implementation of Phase 1. Using the framework for Phase I in an effort to prepare for further implementation of the Smallpox Plan, the Ring Leaders will assess the possible administrative, structural and community issues that might occur in Phase II of the program for a middle-sized health department. The following case study is a quality assurance evaluation of the Middletown, Illinois County Health Department's ability to implement the pre-event smallpox initiative, while still providing essential public health services in the community.

### **Setting of the Case...Background**

September 11, 2001 began a new and difficult era, for America. Prior to that date, attacks against the U.S. by an outside agent had been few and far between – and they did not occur within the borders of our country. September 11<sup>th</sup> demonstrated the vulnerability of America to attacks from enemies. The attack on that date was an overt – demonstration that brought grief and terror to the hearts of millions of US citizens. The attacks that occurred in October were a different type of offensive. To date the attacks remain unsolved. The weapon used was much more insidious – biological warfare – this time with weapons-grade anthrax. But the letters to the US Capitol, to a tabloid in Florida, media outlets in New York and to an elderly Connecticut woman brought the realization to the United States that the next attack did not have to be an explosion or another overt “big show” action. It could be quiet and from far away and it could be even more deadly than the destruction of the World Trade Center. The United States began preparing for a biological attack on its homeland.

On December 13, 2002, President George W. Bush announced the beginning of a voluntary program to provide vaccination to a targeted group of individuals against smallpox. Phase I of the program would provide vaccinations for public health and health care response teams at hospitals. This would allow for pre-event coverage of persons who would be vital in addressing any future outbreak of the disease resulting from a terrorist attack. While smallpox was eradicated from the world in the 1970s, public health professionals and military bioterrorism experts expressed trepidation that nations harboring ill-will against the United States possess this deadly disease and were willing and capable of infecting thousands and even millions of people.

With this new mandate, health departments across the US face an even greater responsibility and challenge to provide health services in their communities. In addition to their daily duties to ensure the public health, the President’s announced implementation of a national Pre-Event Smallpox Initiative laid a very significant additional burden on the public health system. The federal government released little information regarding the phases for the plan beyond Phase I, but did indicate that a Phase II would include all hospital workers and first responders (police, fire and paramedics) with nationwide totals reaching in the millions. This initiative will stretch the capacity of all health departments – large and small.

The Illinois Department of Public Health (IDPH) required each county health department to submit a plan for implementation of Phase 1. Using the framework for Phase I in an effort to prepare for further implementation of the Smallpox Plan, the Ring Leaders will assess the possible administrative, structural and community issues that might occur in Phase II of the program for a middle-sized health department. The following case study is a quality assurance evaluation of the Middletown, IL County Health Department’s ability to implement the pre-event smallpox initiative, while still providing essential public health services in the community.

### **About Middletown: The target population**

Middletown County Public Health Department is a mid-sized certified health agency serving a population of approximately 500,000. The health department has been in existence for more than 75 years. The agency has 100 employees, who work out of one central location in the county, providing an array of services including personal health, family planning, immunizations, sewer/water and food sanitation programs. Recent crises, such as dealing with West Nile virus and the threat of war, have resulted in backed up workloads and a weary staff. Early retirement incentives have reduced the trained workforce by 10%. Forty-five percent of the agency staff is nurses, 10% is administrative, 15% clerical/support and 30% is professional, non-nursing staff.

Middletown County has two major cities located adjacent to each other in which 86% of the county's population lives. No municipal health department exists. The population of Middletown County is 76 % Caucasian, 12 % African American, 5 % Latino and 2 % other. The population is also 58 % female, 42 % male.

The area is home to Middletown State University, a mid-sized school. In addition to the University, two large national insurance companies have headquarters in the county. Other major employers include a car manufacturing plant and a chocolate factory.

### **Smallpox Elimination: A History of Public Health Success**

The *Variola* virus, known as smallpox, was once the most feared scourge of society. Each year, smallpox would infect thousands of people, claiming the lives of at least 30% of those infected. Survivors of smallpox often suffered long-term neurological damage and/ or physical deformity. With smallpox being spread from person-to-person through respiratory droplets (coughing, sneezing) and fomite transmission (viral spread through pustular material coming in contact with inanimate objects and being transmitted to another person), control of disease spread was difficult. The only natural reservoir of smallpox is humans, thus allowing it to be eliminated from the world if it could be removed from the human population.

In 1967, the World Health Organization (WHO) took on the mission of eliminating smallpox. To eradicate the *Variola* virus, WHO eradication teams literally chased the virus across the world. While mass vaccination campaigns were conducted, the WHO teams worked to set up surveillance systems for early detection and reporting of smallpox cases in all areas of the world. When a smallpox case was identified, the eradication teams would deploy to the area and use a containment strategy called ring vaccination. For ring vaccination to be effective, the smallpox case must be isolated immediately upon diagnosis. Only individuals who are already immune to smallpox should have contact with the infected individual. Next, all contacts of the smallpox case must be vaccinated and monitored for development of disease. Additionally, all contacts of the primary contacts (first ring) must be vaccinated. If any contact shows signs of developing smallpox, the contact must be isolated immediately and the ring strategy started around the new case and his or her contacts. In 1975, the last case of naturally occurring *Variola major*, the more deadly form of smallpox, was seen in Bangladesh. In 1977, the last case of naturally occurring *Variola minor*, the less deadly form of smallpox, was seen in Somalia. The World Health Organization continued surveillance for smallpox, but never found another case. In 1980,

the World Health Assembly officially certified the world to be free of smallpox; it had been successfully eradicated.

To prevent the re-emergence of smallpox, two places in the world were designated as the official repositories of the smallpox virus; the Centers for Disease Control and Prevention in Atlanta, Georgia and the Institute of Viral Preparations in Koltsovo, Russia. The United Nations instructed all nations to either destroy their smallpox virus stocks or transport them to one of the two official repositories. At the time, it was believed that all nations complied with this directive.

The last case of smallpox in the United States occurred in 1949. Routine vaccination of the population continued until 1971, after which time WHO recommended the vaccine for certain healthcare workers, scientists and military personnel. The military discontinued vaccination in 1989. Full immunity to smallpox lasts between 3-5 years, leaving our nation overwhelmingly susceptible to smallpox.

### **Pre-Event Smallpox Vaccination: An Overview of Public Health's Conflict**

The issue of whether or not to vaccinate against smallpox in the absence of a confirmed case is a debated topic. The risk of smallpox re-emerging as result of a biological weapons attack is unknown. There is no known credible piece of information that details the exact risk of a smallpox attack, although intelligence sources feel that the risk of a smallpox release is real and highly possible.

This dynamic places public health departments in a unique situation. Unlike other vaccines routinely administered in the United States, the smallpox vaccine has a high rate of complications, some of which are potentially life threatening. There currently is not an imminent threat of the disease. Public health departments must weigh the risks and benefits of providing the vaccine, while dealing with a myriad possible health, administrative and legal concerns. The following outlines some of these issues.

#### *Health Complications*

Complications from the smallpox vaccine include the following:

**Inadvertent inoculation** is the accidental implantation of the Vaccinia virus to a site other than the primary vaccination site by autoinoculation or inoculation of a contact. This occurs most frequently in small children around the mucocutaneous borders. Mild cases resolve without treatment.

**Bacterial infections** at the vaccination site are not common, but can occur if occlusive dressings cause site maceration or the site is manipulated and contaminated. The most common organisms to cause infection are Staphylococcus aureus and Group A Beta Hemolytic Streptococci. Children are at greatest risk of this type of complication due to difficulty in not touching the site. This complication is usually mild and treated with antibiotics.

**Eczema Vaccinatum** is caused by implantation of the *Vaccinia* virus into the diseased skin. It occurs in person and vaccine contacts with both active and a history of eczema. This complication is usually severe, causing extensive scarring. It may be fatal.

**Erythema multiforme** is the toxic or hypersensitivity rash that may occur 1-2 weeks post vaccination. This complication is usually benign, but may cause severe itching and discomfort.

**Generalized vaccinia** is the bloodborne dissemination of the vaccinia virus. Within a week of vaccination, lesions appear and undergo rapid evolution ending in scarring. This complication is usually benign.

**Progressive vaccinia** usually occurs in a T-cell deficient person (HIV/AIDS, cancer, immunosuppressive therapy). With this complication, the primary vaccination site fails to heal and spreads locally and by bloodborne dissemination to other parts of the body. Though this complication was rare in the past, it was frequently fatal.

**Vaccinia keratitis** is the implantation of vaccinia virus into diseased or injured conjunctiva and cornea resulting in ulceration and corneal cloudiness. This complication can be treated with antiviral agents. Without treatment, outcomes will be severe.

**Post-vaccinial encephalitis** is a vaccine-associated swelling of the brain. It usually appears 10-14 days after vaccination and can cause life-threatening complications. This occurs in 15 individuals per million first time vaccinees. Young children are at greatest risk for this complication.

**Death** occurs in at least one case per million vaccinees.

The smallpox vaccine does not contain the *Variola* virus, rather it is made from the *Vaccinia* virus. *Vaccinia*, commonly known as cowpox, and *Variola* virus both belong to the orthopox family. An individual who is immune to *Vaccinia* is also immune to *Variola*.

The medical status of the United States population has changed significantly since the last time smallpox vaccine was routinely given. HIV and AIDS cause immunosuppression in both diagnosed and undiagnosed people. Organ transplant recipients take immunosuppressive medications to prevent rejection. Chemotherapy and radiation, used to treat cancer, cause immunosuppression. The incidence of eczema and asthma has increased.

Prior to vaccinating an individual, it must be determined that the individual prepared to be vaccinated does not have a contraindication. Additionally, it must also be determined if a close personal contact of the potential vaccinee has a contraindication since the smallpox vaccination site contains live *Vaccinia* virus, which can be spread to another person through contact with the site, until the scab falls off 21-28 days post vaccination.

Phase I vaccinations was carried out in populations generally more aware of the issues related to a vaccine of this type. Knowledge of contraindications, site care issues, transmission issues and

attention to reactions would be better known in the Phase I targeted population. So while the Phase I volunteers would work as a good control and testing group, the issues take on a greater significance and a greater possibility for error with a larger population. The intended target for Phase II is all “first responders”: fire fighters, police officers, hospital and medical center staff, emergency medical technicians and family members of these groups.

### *Confidentiality and Liability*

Some of the conditions that are contraindications to being vaccinated have negatively associated societal perceptions and cannot be determined through physical observation of the potential vaccinee or vaccinee’s contact, leading to the possibility that some individuals may not fully disclose their medical status.

Those who conduct pre-vaccination screening to determine vaccination eligibility are charged with screening out those individuals with a contraindication, but must rely on the answers provided by the potential vaccinee. If the potential vaccinee does not disclose a medical condition, is unaware of an undiagnosed medical condition or that of a close personal contact, administration of the smallpox vaccine may have a potentially devastating outcome. To what extent do those running the vaccination clinics have to go to ensure that all vaccine recipients can safely receive the vaccine? Should the health department implement mandatory HIV testing; pregnancy testing; physical exam; personal physician sign-off certifying the individual does not have a contraindications?

Public Health departments soon realized that taking on the President’s pre-event smallpox initiative could leave vaccinators and their sponsoring agency liable for any problems associated with the vaccine and its administration. Section 304 of the Homeland Security Act does answer a few of these questions, stating that “officials, agents, or employees are also covered for actions arising out of the administration of a countermeasure” but ultimately, each state was required to determine its own interpretation of this issue. The Centers for Disease Control and Prevention (CDC) states that:

Section 304 provides an exclusive remedy against the United States for injury or death attributable to smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin ("smallpox countermeasures"). This means that no claim for liability for injury or death attributable to a smallpox countermeasure could be brought against entities or individuals who are covered by Section 304's protections. (Dec 13, 2002)

States were also required to determine if Section 304 would authorize payment for lost time from work or health care costs necessary for treating the injured. Again the CDC reports on Section 304:

If a claimant prevails on a Section 304 claim, damages would be determined according to state law, within any limits imposed by federal law. While loss of income and health care costs generally are recoverable, Section 304 does not establish a "no-fault" compensation program. Individuals may wish to review their health insurance policies to determine whether they cover health-care costs for injuries attributable to administration of a smallpox countermeasure.”

State and local health departments were left with the charge of insuring that these issues were sufficiently addressed, in order to proceed with the initiative.

### **The Middletown Experience :**

Despite the many potential problems with implementing the pre-event smallpox initiative, Middletown decided to participate in the program. To overcome staff shortages and to maintain other clinic services, Middletown collaborated with neighboring counties to share resources. The following details some of the logistics of the implementation plans.

#### *Phase I Plan*

Middletown collaborated with a planning area that consists of seven counties surrounding and including Middletown. Each county has a local health department. As such, staff from their agency developed a clinic plan that provided a smallpox vaccination clinic two mornings per week for six weeks for local health department staff in Middletown and the surrounding county health agencies, as well as for the hospital smallpox response care teams in the counties in the local planning area. A total of 28 area-wide local health department personnel indicated an interest in vaccination within the program. In the seven counties there are a total of four hospitals that made the decision to participate in Phase I that brought an additional 100 persons as potential vaccinees. Four other hospitals delayed their participation in the program pending the resolution of issues related to liability and worker's compensation coverage.

On average, 13 people were vaccinated at each clinic day for five weeks. Individuals were told to expect to be in the clinic for approximately two hours in order to complete the entire process. In order to accomplish this activity, six staff people were dedicated to the clinic for a total of 4.5 hours each clinic day. Three of these individuals had been vaccinated and were legally able to vaccinate others under their licensed status. Staff responsibilities included: registration, history and medical review, consent process and vaccination identification/tracking, vaccination, dressing and post vaccination instructions. Vaccinees who would be working during the 28 days following inoculation needed to be checked prior to beginning work for integrity of the bandage site, as well as for any possible concerns or complications related to the vaccination.

In the case of the Middletown area, the distance between participating agencies and health care facilities necessitated that each facility assess site integrity and "take" at their individual facilities. That information would then be relayed to the Middletown Department, which would be responsible for reporting any complications and the final evaluation of "take" response to IDPH. Each local health agency and hospital participating in the program had designated their own agency contact and coordinators. Those individuals were occupational health coordinators and designated physicians who would provide any care or guidance necessary for participants from their organizations.

#### *Phase I Results*

Of the 128 who volunteered for vaccination, 116 were able to be vaccinated after a full history and potential contraindication review. In two of those cases, there was not an adequate "take" and revaccination occurred. In both of those cases, the subsequent vaccination produced acceptable results. In 39 of the vaccinees, there were complications to a level that required

anywhere between 1 and 4 days off of work. Fever, soreness and malaise were generally found in all of the 39 who missed work. In one case, an individual was hospitalized for four days due to complications, and in 1 other case there was an auto-inoculation to the area around an eye, which required a 1.5 hospital stay and treatment. All of the individuals vaccinated in Phase I were health care professionals – either physicians, nurses, respiratory or laboratory technicians and therapists. While they had at least some background information regarding infection control technique with their positions, all were provided with fairly extensive information and reminders about precautions and recommended actions to lessen the possibility of infection related to the vaccination site.

While Middletown had experience in providing vaccination/immunization services, additional training and education was required for staff, specifically in regard to smallpox vaccine and its general course.

### **Where do we go from here: Pre-Event Smallpox Vaccinations, Phase II**

With Phase I completed in May, the federal government announced the opening of the next Phase of the program. This program was announced to be intended to start July 1. Phase II implementation would mean a much larger number of individuals may request vaccination. While many of the surrounding local health departments would be providing similar services to the first responder and hospital communities in their areas, two had decided that they could not put a clinic into operation. Therefore, Middletown would be the logical agency to take up the slack from those two areas. Additionally, while they did not participate during the initial Phase, two of the remaining hospitals decided that they could now participate in the program and requested vaccination during the initial stages of Phase II.

Middletown County's first responder community consisted of 10 local fire protection districts with a total 2600 volunteer and paid fire fighters; 12 local police agencies with 78 officers plus administrative staff; and three ambulance companies that served the county-area with approximately 50 medics. Additionally, the two remaining hospitals requested vaccination of 50 persons each, for a total of approximately 3000 individuals who would be potential vaccinees for Phase II.

There is a significant variation in the number of individuals who would be vaccinated from Phase I to Phase II. Where Phase I required Middletown County to conduct clinics to accommodate less than 200 people over a six week period, Phase II will mean 3000 individuals will need to be vaccinated. The time period for this number is limited to 16 weeks.

In developing its plans to implement Phase II, Middletown Health Department attempts to balance the varying factors and continue to provide daily public health services, while accomplishing the added responsibility of a new major program. Primary concerns in Phase II development include: maintenance of programs with added staff demands, assurance of appropriate and adequate information to potential vaccinees for decision making and appropriate follow-up and tracking of vaccinated persons.

## **The Case Study: Development and Implementation of a Plan for Phase II**

Basing their activities on recent experience, the management of Middletown Health Department determined that in order to vaccinate the number of individuals eligible for Phase II, they would need to conduct smallpox clinics four full days per week for 14 weeks and inoculate 57 individuals through the clinic each of those days. Accomplishing that very weighty goal would require a focus in at least two primary areas:

- Training and redirection of a large percentage of the agency staff in one or another area of clinic operations for the time period of Phase II
- Communication / coordinated public health message

Middletown administration put together an implementation team consisting of the Director of Nursing Services, the health agency Administrator, the Chief Public Health Educator and the agency Occupational Health Officer.

The implementation group adopted the process that had been used for Phase I and applied it to the Phase II effort. In doing so, informational packets were provided to each of the facilities that would be participating in the program. Middletown Health Department instructed the participating facility management to provide those packets to their personnel interested in getting the vaccine at least five days in advance of the scheduled clinic.

For efficiency's sake, the health department designated the following clinic schedule:

- Monday - fire service agencies;
- Tuesday - police agencies;
- Wednesday - ambulance providers; and
- Thursday - hospital personnel.

Development of the vaccination list and the scheduling for employees to be vaccinated was left to the participating facility within those restrictions and was then forwarded to the health department for inclusion in the master schedule.

Personnel to be vaccinated would be directed to come to the clinic on their scheduled vaccination date and would then go through the following steps:

- Registration
- Provision and Review of Informational Packet
- Medical History and Informational Packet Screening Process
- Administration of Informed Consent for Vaccination
- Vaccination
- Site Dressing
- Post Vaccination Care Instruction/including scheduled date for "take check"

Because of the scope and type of this particular vaccine, the public health department felt that the local health assigned physician should be the primary point of contact for any complication,

question or concern related to a vaccinee. Additionally, the agency felt that the evaluation of “take” should be done at the health department for consistency and follow-through on reporting.

The implementation group developed a general information guide/packet on smallpox and the vaccination. This information was distributed to the local media, as well as hospital administration for general public consumption.

On June 1, all pertinent information was distributed to all local area first responder organizations in the planning area, as well as hospitals. Informational meetings were scheduled to be held June 15, 16, and 17 for the administration of those entities, as well as potential vaccinees. The meetings were intended to provide basic information about the program and the vaccination process. The educational programs were conducted by the Middletown Health Department Administrator and the Health Educator.

Staff training for Middletown Health Department employees who would be assigned to this activity was scheduled for June 9. The training would provide an overview of the program and expectations of clinic operations and staff roles. In addition to six (6) nursing staff, two (2) clerical support staff and one (1) physician were expected to be staffing the clinics at all times. This training session included a “dry run” of the clinic operation utilizing unassociated agency staff as the play “vaccinees”.

On July 1, the first clinic was opened at 9:00 am. Between opening and lunch only 5 individuals came in for vaccination – all from the neighboring Hickernoodle Fire Protection District. After the process had been completed on 4 of the individuals from this fire house, it was discovered that these 4 were more than 50% of their fire department’s personnel force. Two of the firemen were coming off of a 48 hour shift and two would be going on after their vaccination for a 48 hour shift.

## **Study / Discussion Questions for Phase II:**

1. Were the correct individuals included on the implementation team? Would input from affected groups have added valuable information to the process?
2. What considerations are there in vaccination for first responders that may not exist for public health response teams? Review the attached International Firefighters Association Guidance on Smallpox Vaccinations (Appendix). Did Middletown address all the issues reviewed by the IAFF? What did Middletown include or fail to include in their plan implementation?
3. Was the education process for entities and the individual participants sufficient? How could it have been improved? Did the public health department provide enough information and access to information before and after the vaccination phase implementation?
4. How can communications be used to increase participation in this type of program? What should the public health message be about first responders receiving the smallpox vaccine?
5. In a diverse population, how do you ensure that potential vaccinees have read and understand the significance of the possible complications and contraindications to them and their close contacts?
6. Were the staff and employees of the health department agency utilized in the most efficient manner to provide this and the other agency services during this period?
7. What information is necessary to ensure there is awareness of the needed precautions for the site in order to avoid accidental inoculation?
8. Discuss the potential resources that exist outside of the Middletown County Public Health Department (University staff, staff employed by the 2 large insurance companies, local hospitals, pharmacies, fire department, police dept., etc) that could collaborate on developing the plan to deal with this problem. Could community assets have been tapped to assist in this extraordinary program?
9. Are there special staff training needs for this type of program? What additional training needs to be done to prepare the workforce?
  - General Smallpox Awareness (all employees participated)
  - Current Status of Planning
  - Smallpox Immunizations
  - Knowledge and Skill Building (focused on specific knowledge acquisition based on assigned roles)
  - Clinical procedures

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- Recommendations for Using Smallpox Vaccine in the Pre-event Setting, MMWR Feb. 26, 2003/ Vol.52, 1-16.
- State Response Plans and Guidelines, Version 3 at [www.bt.cdc.gov/agent/smallpox/response-plan/index.asp](http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp)

## Appendix

### ***International Association of Fire Fighters Guidance on Smallpox Vaccinations***

The government of the United States believes that there is a threat of a possible biological attack on our civilians utilizing the smallpox virus. Smallpox has significant health effects, including death, for those exposed.

There is no treatment for smallpox and the only effective way of preventing the disease is vaccination. However, there are also serious complications and contraindications associated with smallpox vaccination.

The decision whether to receive the smallpox vaccine is a personal one for IAFF members and other first responders. The goal of this document, prepared by the IAFF, is to provide every IAFF member with the best possible information on smallpox vaccination so each fire fighter and other first responder can make an informed and educated decision based on his or her individual circumstances.

Besides insuring that the employer has adopted a comprehensive vaccination program, each IAFF member must thoroughly review the pros and cons of smallpox vaccination outlined in this document. It is your health and, in some cases, your life at stake – and no one can make that decision but you.

#### **Why Smallpox and the Vaccination Can Be Dangerous**

Smallpox is an acute, contagious disease that can be fatal in up to 30% of those who contract it. Survivors are usually scarred and in rare cases may be blinded. The virus is usually spread from person to person through close contact.

The smallpox vaccine has known complications and known side effects. Most people will experience mild reactions that include a sore arm, fever, and body aches. It has been reported that 1 out of 3 vaccinated individuals will miss time from work, school, or recreational activities. It has been estimated that for every million people vaccinated, 15 will have life-threatening reactions, and one or two deaths will occur.

In addition, there are individuals who are at high-risk for complications from the vaccine and should not be part of the vaccination program. Persons with conditions such as suppressed immune systems (either through disease or treatment); with eczema or atopic dermatitis; acute, chronic or exfoliative skin conditions; or that have a moderate or severe short-term illness should decline the vaccine. In addition, those that are pregnant, plan to become pregnant within one month, or are breast feeding; that are allergic to the vaccine or any of its ingredients; or have a history of chronic use of steroids are also at significant risk for complications.

**However, fire fighters, emergency medical personnel and other first responders that are exposed to smallpox should get the vaccination, since the risk of smallpox outweighs the complications associated with the vaccine.**

***The IAFF will continuously update this information as more data is generated and as conditions change.***

## **Factors You Must Consider**

Here are some of the factors that must be considered:

- Do you reside in an area that is at a perceived risk for a terrorist attack?
- Do you understand that there is no treatment for smallpox?
- Have you studied the adverse impacts of smallpox vaccination outlined in this document?
- Do you have any health conditions, as outlined in this document, which may adversely affect your reaction to the vaccine?
- Do your household contacts or co-workers have any health conditions, as outlined in this document, which may adversely affect them if you are vaccinated?
- Has your decision been thoroughly discussed and reviewed with your family?
- Has your employer adopted a comprehensive vaccination program, including training and medical monitoring, as recommended by the IAFF?
- Has your employer addressed the issue of compensation and leave for individuals that experience adverse reactions from the vaccine?
- Are you, your family, and your employer prepared to deal with any adverse reaction that may result from receiving the vaccination?

## **Comprehensive Smallpox Vaccination Program**

**The IAFF believes that before any vaccination program is initiated by the employers of our membership, each of the IAFF-endorsed provisions detailed below must be fully implemented.**

The IAFF advises all of its members not to proceed with smallpox vaccinations if your employer fails to agree to this comprehensive smallpox vaccination program, which has been derived from and is consistent with recommendations from the Department of Health and Human Services (HHS), the Centers for Disease and Prevention (CDC), the Department of Defense (DOD) and the Advisory Committee on Immunization Practices (ACIP).

The IAFF recommends that:

- Smallpox vaccinations shall be made available, at no cost, by their employer to all fire fighters and emergency medical personnel and such vaccinations shall be provided while the employee is on duty.
- Fire fighters or emergency medical personnel shall be entitled to decline the smallpox vaccine. Any employee who declines to receive the vaccine shall not be subject to discrimination at work. If an employee declines to receive the vaccination, he/she must

sign a waiver. The waiver shall include the following language (language is consistent with waiver language promulgated by U.S. OSHA for hepatitis B vaccination and Section 4(b)(4) of the OSH Act):

*“I understand that due to my occupation, I may be at risk of being exposed to and acquiring smallpox. I have been given the opportunity to be vaccinated with smallpox vaccine, at no charge to myself. However, I decline the smallpox vaccine at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring smallpox, a serious disease. If in the future I want to be vaccinated with the smallpox vaccine, I can receive the vaccination at no charge to me. My statement of declination of smallpox vaccination is not intended to supersede or in any manner affect any workers’ compensation law or to enlarge or diminish or affect in any other manner to common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment. I also understand that I will not be discriminated against by my employers if I decline to be vaccinated.”*

- If an employee initially declines vaccination but decides later to get vaccinated, the employer shall make the vaccine available at no cost. If at some point the U.S. Public Health Service recommends that people who have had the vaccination should be revaccinated, they shall be made available to all employees at no cost.

### **Training for First Responders**

Prior to vaccination employees shall receive training, which shall be provided at no cost during working hours to all fire fighters and emergency medical personnel. The training must include at a minimum:

- General explanations of the epidemiology and symptoms of smallpox;
- Specific information on how smallpox is transmitted, including modes of delivery as a weapon;
- Actions and procedures to be followed in the event of exposure;
- The employer's exposure control plan and how the employees can obtain a copy;
- Information on how to recognize tasks that may involve exposures to smallpox;
- Up-to-date information on the *vaccinia* (smallpox) vaccine;
- The method of vaccination and the spectrum of normal and adverse vaccination reactions, including the benefits, the risks and the fact that it is provided at no cost to the employee;
- Risks to non-vaccinated family members and fellow employees;
- Specific information on vaccination-site care;
- Copies and explanation of all CDC and DOD protocols on the subject of smallpox;
- A description of the post-exposure evaluation;

- The methods (and limitations of those methods) that may prevent exposures to smallpox, including personal protective clothing and equipment (PPE), work practices and decontamination;
- The selection of appropriate PPE; and
- The proper use, location, removal, handling, decontamination and disposal of PPE.

### **Medical Monitoring**

It is essential to medically screen vaccine recipients, their family and fire station contacts for contraindications before vaccination to prevent serious complications. While the standard of practice for all immunizations requires medical screening, smallpox vaccination is unique in that there is a need to screen for risks among family/household contacts and employee contacts in the fire station.

Prior to vaccination the employer shall provide medical screening to ensure the vaccine is not contraindicated for medical reasons. Such reasons shall be:

- Weakened immune system (Note: cancer treatment, an organ transplant, HIV, or medications to treat autoimmune disorders and other illnesses can weaken the immune system).
  - Any fire service member who is concerned that they could have HIV infection may request and the employer shall provide confidential HIV testing. The confidential results shall be reported to the potential vaccinee before vaccination, and the results of the test and the fact that the test was requested shall remain confidential and not recorded in the medial file.
  - HIV testing is recommended for anyone who has a history of risk factors for HIV infection or is not sure of his or HIV-infection status. Anyone who is concerned that they may be HIV-infected should request confidential screening prior to smallpox vaccination.
  - Any fire service member who has a weakened immune system due to medical treatment (i.e. cancer drug or radiation) or chronic steroid use.
- Employees with eczema or atopic dermatitis should not get the vaccine even if the condition is not currently active, mild or experienced as a child;
- Acute, chronic or exfoliative skin conditions such as burns, chickenpox, shingles, impetigo, herpes, severe or uncontrolled acne or psoriasis. Employees with any of these conditions should not get the vaccine until the condition has resolved or a physician affirms it is under maximal control. However, employees with contraindicated skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision making;

- Pregnancy or plans to become pregnant within one month of vaccination. Vaccine shall not be provided during pregnancy nor shall it be provided to employees who live in a household with a pregnant individual; and
  - Women of childbearing potential shall be provided with screening/questioning for pregnancy before receiving immunizations. Any woman who is uncertain about pregnancy status shall be medically tested for pregnancy before immunization. Vaccination shall be deferred for pregnant women at least until resumption of full duties following pregnancy, or later as postpartum care may require, or while they are currently breastfeeding.

In addition, individuals should not get the smallpox vaccine if they:

- Are allergic to the vaccine or any of its ingredients.
- Have a moderate or severe short-term illness. These people should wait until they are completely recovered to get the vaccine.
- Have a history of chronic use of steroids.

Employees who have any of the above conditions, or live with someone who does, should NOT get the smallpox vaccine unless they have been directly exposed to the smallpox virus.

**If directly exposed to the smallpox virus, fire fighters and EMS personnel who were not vaccinated should get the vaccine immediately, regardless of their health status. If exposed, the risk of smallpox outweighs the complications associated with the vaccination. After an exposure, any non-vaccinated employee must be quarantined until vaccinated and medically released.**

### **Vaccinations**

The vaccine shall only be made available after the employee has received the required training and after the employee has been medically evaluated.

Vaccinations are to be given by or under the supervision of a licensed physician or other health care professional according to the recommendations of the U.S. Public Health Service. The employer shall ensure that health care professionals used for vaccinating their employees remain alert to modifications in clinical recommendations as the smallpox vaccination program progresses. The employer shall implement a quality assurance program to assess vaccination technique of vaccinators.

The vaccination is usually provided at the deltoid muscle of the non-dominant arm, avoiding any skin conditions, tattoos or skin folds. The vaccination consists of three (3) punctures with a bifurcated needle for individuals who were never vaccinated or fifteen (15) punctures for those who have been previously vaccinated or for vaccination retakes.

An assessment of vaccine take is required for all vaccines. The employer shall ensure that medical personnel trained in vaccination evaluation inspect the vaccination site of all vaccinees at six (6) to eight (8) days after vaccination administration. All employees shall be instructed to report if they do not develop a characteristic smallpox vaccination reaction.

If a characteristic vaccination reaction does not manifest within six (6) to eight (8) days after smallpox vaccination, the employee shall be provided with revaccination. Such revaccination shall only be repeated once. For those individuals who do not respond to vaccination with a visible skin lesion, referral for immunologic evaluation is required.

### **Adverse Reactions**

Any individual who experiences any adverse reaction from the smallpox vaccine shall be provided with immediate medical and follow-up care at no cost to the employee.

Any fire fighter or emergency medical personnel who has an adverse reaction to the smallpox vaccine and is unable to perform his/her duties shall be entitled to receive occupational disability benefits as provided by the employer for on-duty injuries/illnesses for the duration of the disability. Any leave of absence associated with an adverse reaction shall be immediately classified and treated as a line-of-duty injury. All medical costs associated with the vaccination and adverse reaction treatment shall be borne by the employer.

*The IAFF will continue with legislative effects that will provide a fair compensation system – like the federal Vaccine Injury Compensation Fund – to assist our members and their families who may be injured from receiving the vaccine or coming into contact with someone who received it. Vaccine manufacturers and those who administer it have been offered immunity from liability through recent Homeland Security legislation.*

If an employee experiences any adverse reaction to the vaccine, the employer shall immediately file a Vaccine Adverse Event Reporting System (VAERS) form. Additional information on filing a VAER report can be found at the following CDC/FDA Web site: [www.vaers.org](http://www.vaers.org).

## Vaccination-Site Care

The virus used in the vaccination (*vaccinia*) can be cultured from the site of the vaccination beginning at the time of development of a papule (two to five days after vaccination) and until the vaccination scab separates from the skin. During this entire period, the employee must care for the site to prevent spread of this virus to another area of the body or to another person through inadvertent contact.

Site care will also assist in preventing any secondary infection. High-risk individuals may be especially vulnerable to virus shedding and scab particles from a vaccinated employee during the post-vaccination healing period.

Hand washing is the most important measure to prevent inadvertent contact spread from vaccination sites. Hands must be washed after any touching of the vaccination site area with soap and water or when unavailable with an alcohol-based waterless antiseptic solution.

The employer shall evaluate and direct any fire or EMS activities (including emergency response and training) that may subject employees' vaccination sites to undue pressure (may burst a pustule), rubbing or prolonged immersion in water (may cause tissue breakdown or secondary infection). Many fire or EMS activities, including donning and doffing heavy protective clothing, donning and doffing SCBA, carrying heavy objects (hose or high-rise packs), and leaning against walls while using hose lines at a fire may lead to injury of the vaccination site.

The employer must defer any non-emergency activities, including training, that may complicate vaccine site care and cleanliness. Any vaccination site injury must be reported, immediately evaluated, and if necessary treated by medical personnel. General vaccination site care recommends leaving the site unbandaged. However, for fire and EMS personnel, bandaging may be more appropriate to help reduce spread and accidental infection.

Prior to initiating a small-pox vaccination program, fire departments must develop plans for: site-care stations; personnel to monitor employees' vaccination sites; procedures and training to promote effective bandaging; procedures and training for scrupulous hand washing hygiene; and bio-hazardous waste procedures for disposal of contaminated bandages and dressing, as well as laundering decontamination procedures for clothing (bleach shall not be used for protective clothing), towels, sheets or other cloth materials that have had contact with the site.

The employer must provide employees with occlusive (wound-sealing) dressings, such as semi-permeable polyurethane dressings (e.g. Opsite® or Tega Derm®). Be aware that occlusive dressings, including non-permeable (hard) or semi-permeable (i.e. polyurethane) coverings, allow for the accumulation of viral contaminated exudate, which requires extra care when removed to prevent viral contamination. Also fluid can accumulate under such dressings, which may increase the maceration of the vaccination site. Occlusive dressings require the vaccination site to first be covered with dry gauze and then applying dressing over the gauze.

Fire fighters are involved in arduous work in wet environments. If the employee becomes wet from their environment or from perspiration, any clothing, bandage, and/or dressing must be removed as soon as practical and replaced with clean clothing and dressings.

*The IAFF and our medical advisors will be investigating alternative vaccine administration sites (i.e. lower medial or lateral thigh) for fire fighters and EMS personnel.*

### **Family, Patient and Co-worker Contacts**

The employer is required to develop procedures to minimize contact of newly vaccinated employees with unvaccinated employees and the public.

For employees who have risk factors and accordingly have not been vaccinated, the employer shall ensure that they are physically separated and exempt from activities that pose the likelihood of contact with recently vaccinated employees and potentially infectious materials. Employees with contraindications to vaccination shall not share or use common sleeping space, linens, towels, protective clothing (e.g. protective clothing) and equipment (SCBA, etc.) with employees who have been vaccinated.

- The employer must make provisions for pregnant fire fighters and emergency medical personnel to ensure they are not exposed to vaccinated employees.
- The employer must make provisions for immuno-compromised fire fighters and emergency medical personnel to ensure they are not exposed to vaccinated employees.
- The employer must ensure that non-vaccinated fire fighters and emergency medical personnel with eczema, atopic dermatitis, or acute, chronic or exfoliative skin conditions are not exposed to vaccinated employees.

The employers shall formally educate employees through procedures and training, of the risks of close physical contact with family members, including those who may have risk factors and infants less than one year old. Employees must be instructed that, while off-duty, vaccination site care (including bandaging and wearing of long sleeved shirts) must continue and that continued hand-hygiene is essential.

The employer shall also inform employees that blood donations must be deferred until the scab spontaneously separates from the vaccination site or if the scab is otherwise removed, blood must not be donated for at least two months after the date of vaccination. Any employee who had any vaccine complication must defer donation of blood until fourteen (14) days after complications have been completely resolved.

### **Recordkeeping**

The employer is required to **maintain records** according to the following schedule:

- **Medical records** (including the employee's name, social security number, smallpox vaccination status, all examinations and evaluations, healthcare professionals' written opinions, and information provided to the healthcare professionals) for the duration of employment, plus at least 30 years; and
- **Training records** for three (3) years from the date on which the training occurred. Medical records are confidential and may not be disclosed or reported without the employee's written consent. Medical records are to be available to employees and to

anyone having written consent of the employees upon request. Training records are available to the employee or employee representative upon request.

## Resources

The following resources support the above information and recommendations. These organizations' web sites provide additional information and recommendations on smallpox and the smallpox vaccination. The list provides links to governmental and non-governmental sites dedicated to vaccines, immunization practices, and vaccine safety.

- Centers for Disease Control and Prevention (<http://www.bt.cdc.gov/agent/smallpox/index.asp>)
- National Library of Medicine/National Institutes of Health (<http://www.nlm.nih.gov/medlineplus/smallpox.html>)
- World Health Organization (<http://www.who.int/emc/diseases/smallpox/factsheet.html>)
- American College of Physicians/American Society of Internal Medicine (<http://www.acponline.org/bioterro/index.html>)
- Agency for Healthcare Research and Quality (<http://www.bioterrorism.uab.edu/EIPBA/Smallpox/moreExtInfo.html>)
- American Medical Association (<http://www.ama-assn.org/ama/pub/category/6206.html>)
- Department of Defense (<http://www.vaccines.army.mil>)
- Vaccine Healthcare Center (<http://www.vhcinfo.org>)
- US Food and Drug Administration (<http://www.fda.gov/cber/products/smawye102502.htm>)
- New England Journal of Medicine: Smallpox and Smallpox Vaccination (<http://nejm.org/earlyrelease/early.asp>)

## Background Information

### Fire Fighters/EMS Personnel and Smallpox

Smallpox is a serious, contagious, and sometimes fatal infectious disease. There is no specific treatment for smallpox, and the only prevention is vaccination. Smallpox can cause a severe rash covering the whole body that can leave permanent scars, high fever, severe headache or backache, dizziness, severe abdominal pain and delirium.

Smallpox kills about three out of 10 people infected. The incubation period is seven to 17 days, yet the infected individual would not be contagious until the appearance of a rapidly spreading rash. If the infected individual survives, contagion lasts until the very noticeable scabs from smallpox pustules have completely healed, which usually takes three weeks.

Smallpox is usually spread by contact with infected persons. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. Smallpox also can be spread through direct contact with infected bodily fluids or contaminated objects such as bedding or clothing.

Historically, indirect spread was less common. Rarely was smallpox spread by virus carried in the air in enclosed settings such as buildings, buses, and trains. Smallpox is not known to be transmitted by insects or animals. However, the deliberate release of smallpox as a weapon of

mass destruction is now regarded as a possibility, and the United States is taking precautions to deal with this potential terrorism threat.

In the United States, routine vaccination against smallpox ended around 1972. In May 1980, the World Health Organization declared the global eradication of smallpox as a naturally occurring disease and recommended that all countries cease vaccination. Military smallpox vaccination programs continued longer. In 1984, routine military vaccinations were limited to recruits entering basic training. This practice was discontinued in 1990.

In the wake of the terrorist attacks of September 11, 2001 and the subsequent anthrax letter attacks, the U.S. government reassessed the threat of a smallpox attack. The resumption of a smallpox vaccination program is intended to ensure that the first responders, including fire fighters and emergency medical personnel, can achieve its missions in case smallpox is used as a biological weapon.

On Friday, Dec. 13, 2002, President George W. Bush announced that smallpox vaccinations are to be provided for the military as well as medical professionals, emergency responders and response teams that will be the first on the scene at a biological attack. The President recognized that first responders – our Nation’s fire fighters and emergency medical personnel – are first on the scene and will assist in the treatment of civilians in a crisis. To do this job effectively, the President declared that fire fighters and emergency medical personnel should be protected against the disease.

The President’s program includes a three-phase implementation plan. Phase One vaccinations would be provided to public health staff and key health care workers at local hospitals who might be called upon to treat and manage initial smallpox cases. Fire and emergency medical personnel with the potential for exposure will be included in Phase Two of the vaccination program. Phase Three will involve immunizations to the public; but, the details of this phase are not yet available.

The smallpox vaccine helps the body develop immunity to smallpox. The vaccine is made from a virus called *vaccinia*, which is a “pox”-type virus related to smallpox. The smallpox vaccine contains the “live” vaccinia virus-not dead viruses like many other vaccines. For that reason, the vaccination site must be cared for carefully to prevent the virus from spreading.

Historically, the vaccine has been effective in preventing smallpox infection in 95% of those vaccinated. In addition, the vaccine was proven to prevent or substantially lessen infection when given within a few days of exposure.

The smallpox vaccine is not given as a shot with a hypodermic needle. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is used to prick the skin a number of times in a few seconds, usually in the upper arm. The pricking is not deep, but it will cause a sore spot and one or two droplets of blood to form.

If the vaccination is successful, a red and itchy bump develops at the vaccine site in three or four days. In the first week, the bump becomes a large blister, fills with pus, and begins to drain. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third week, leaving a small scar.

## **Vaccine Complications**

For about three weeks, the vaccination is highly contagious and can cause infection in the person who received the vaccine or other people in close contact. Fever is common after the vaccination. Generalized rashes and secondary pyogenic (pus-producing) infections at the site of the vaccine may also occur. Inadvertent vaccination at other sites is the most frequent complication, which usually results from autoinoculation of the vaccinia virus which was transferred from the vaccine site. The most common sites are the eyes face eyelids, nose, mouth, genitalia and rectum. Accidental infection (autoinoculation) of the eye may lead to blindness. Again, prevention includes vaccine site management and hand hygiene.

Generalized vaccinia among persons without any underlying illness may occur. It is characterized by a rash, which is usually self-limited and usually requires no therapy, except among individuals whose conditions appear toxic or those that have a serious underlying illness.

More serious complications that may follow vaccination include inflammation of the brain (encephalitis) and spinal column (encephalomyelitis) which is characterized by an influx of cells, dysfunction of the brain associated with confusion and decreased mental capacity (encephalopathy), systemic (total body) vaccinia infection (progressive vaccinia) and extensive scaling of the skin on which vaccinia infection is superimposed (eczema vaccinatum). These complications, which are rare, may result in severe disability, permanent neurological sequelae and/or death. Death most often results from post vaccination encephalitis or progressive vaccinia. Approximately 1 death per million primary vaccinations and 1 death per 4 million revaccinations have occurred after smallpox vaccinations. Deaths have also been reported in unvaccinated contacts of individuals who have been vaccinated.

In revaccinated individuals, the risks of complications have been low. Most complications have occurred in patients with underlying diseases or who have received therapy which impairs the immunologic system or those who have not received the vaccine in many years.

Individuals at risk for experiencing increased side effects from the vaccine are those who have skin conditions such as eczema and/or atopic dermatitis, have weakened immune systems such as transplant patients, are HIV-positive or chemotherapy patients, are pregnant or plan to become pregnant within a month, have known severe reaction to the smallpox vaccine from the past and those with a history of chronic steroid use. Anyone who falls into these categories or who lives with individuals in these categories should not receive the vaccine, unless exposed to smallpox.

Accordingly, formal training and medical screening of potential vaccine recipients is essential to ensure that those at risk do not receive the vaccine.

There are two treatments that may help people who have certain serious reactions to the smallpox vaccine. These are: Vaccinia Immune Globulin (VIG) and Cidofovir. Patients receiving these drugs would need to stay in the hospital for observation and possible additional treatment, as the VIG and Cidofovir may cause a number of side effects as well. CDC will review summary reports of adverse events and will investigate all individual reports of serious events.

The federal government has also directed the states to work with hospitals to set up systems to diagnose, manage, and treat people who experience adverse reactions from the vaccine. This will include rapid access to the primary treatment for most serious adverse events.

*The IAFF and our medical advisors will continue to review the progress and any additional problems with the vaccination program as it is implemented in the United States and abroad.*

*The IAFF is consulting with the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) so our membership is protected and prepared to protect the nation in the event of a smallpox outbreak. Further updates on this important issue will be posted on [www.iaff.org](http://www.iaff.org).*