

Impetuous Planning: Creating a Regional Pre-Event Smallpox Vaccination Plan in Two Weeks

A Case Study in Policy Development

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Abstract

In December of 2002, the President of the United States announced a pre-event smallpox immunization initiative to increase the nation's capacity to respond to a smallpox bio-terrorism event. The smallpox vaccine, which was routinely administered to Americans until 1972, is a highly effective protection against the disease when given before or shortly after exposure to the virus. Pre-attack vaccination of specific teams of individuals will allow, in the event of a smallpox attack, to immediately administer the vaccine to others and care for the victims. This initiative is divided into 3 major phases which would offer the smallpox vaccine, on a voluntary basis, to targeted groups, specifically: Phase 1 – public health and healthcare staff; Phase 2 – first responders (fire, police and ambulance personnel); Phase 3 – general public. This national smallpox vaccination plan is being formulated by the Centers for Disease Control and Prevention who, beginning in January of 2003, will initiate the distribution of the vaccine to individual States who in turn will disseminate the vaccine to major local health departments across the state.

This case study will assess the process undertaken by Passion County Health Department in the state of Nevada to implement this initiative for the first 3 months (December 2002 – February 2003). Conclusions will be based upon three organizational practices associated with policy development in public health: 1) Identification of resources in the community, 2) Setting priorities among health needs, and 3) Developing the plan to address priority health needs.

Introduction & Background

With the catastrophic terrorism events of September 11th and the impending war in the Middle East, the United States is taking precautions against further terrorism threats in many areas. One of the primary areas of concern is a biologic attack of some nature. Political pressure and perhaps Intelligence has created an environment where the President of the U.S. is mandating states to immediately develop response plans to such an attack. However, upon issuing this mandate, the federal government was simultaneously finalizing its own federal policy, which would dictate the parameters of each individual state's plans.

Smallpox is a serious, contagious, and sometimes fatal infectious disease. There is no specific treatment for smallpox disease, and the only prevention is vaccination. The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. The incubation period of smallpox (the time between infection and the onset of symptoms) is about 1 or 2 weeks. Smallpox may feel like a cold at first, with fever and general achiness. A bumpy red rash follows a day or two later, mostly on the face, arms, and legs. The rash then blisters and becomes filled with pus. Scabs develop and fall off within 3 or 4 weeks.

A person is contagious about a day before the rash develops and for as long as the rash appears. Smallpox is spread mostly through droplets of saliva that might be released in a sneeze or a cough. It can also be spread through clothing,

sheets, and blankets used by people with the infection. The characteristic smallpox rash makes the disease very easy to diagnose. Most doctors - even those who have never seen a case of it before - could readily identify it.

Smallpox is of particular concern because it is one of the most deadly biological agents and hardly anyone in the U.S., other than a small minority of military and laboratory personnel, is currently vaccinated against it. Smallpox vaccinations are controversial because they are known to cause significant side effects, including death for a very small percent of cases. Once vaccinated, a person is carrying a live virus and can infect others. Due to the vaccine's side effects, many people will not be able to work for several weeks. People with compromised immune systems, who are pregnant or who have a history of eczema are at greater risk of serious side effects.

As the disease was eradicated over twenty years ago, the public has little knowledge of smallpox or its vaccine. Their perceptions of the risk of a smallpox attack vary dramatically as well as their perceptions of the risk of harm to people vaccinated and the people around them. Even public health professionals have many questions and concerns about the current vaccine.

For educational purposes, this case study is an embellished account of the Passion County Health Department's attempt to develop a Regional Pre-Event Smallpox Vaccination Plan, as it revolved around the evolution and development of the state of Nevada's smallpox vaccination plan.

The events that unfold below demonstrate the complications that arise when a policy is not well defined before it is mandated for development at the local level.

Timeline of Events

Nov. 25, 2002: CDC sent all states the “Supplemental Guidance for Planning and Implementing the National Smallpox Vaccination Program”. States were given a deadline of Dec. 09, 2002 for submitting their plans to the CDC.

Nov. 26, 2002: CNN and other national news affiliates report “Bush to announce plan for smallpox vaccinations”.

Nov. 27, 2002, 10:34 AM: The Nevada State Health Department sends an email stating that the CDC will present a “Smallpox Preparedness Satellite Program” via satellite downlink on December 5 and 6, 2002. This email also stated the following: “Should the need for smallpox vaccinations arise, community wide cooperation and coordination will be vital. Therefore, widespread participation in this training by health and medical personnel in local health departments, clinics and hospitals is strongly encouraged”.

Dec. 02, 2002, 12:05 PM: Passion County Health Department Administrator receives via email a notice of a “Smallpox Vaccination Training” scheduled for Dec. 16, 2002 from the Nevada Health Department.

Dec. 03, 2002: Passion County’s Health Department Administrator sends an email to the original, larger, smallpox-planning committee. The email stated that the Smallpox Response Planning Group was reduced in size. It also stated that the group would be working on planning for two scenarios: emergency and non-emergency vaccination clinics.

Dec. 04, 2002, 8:00 PM: Passion County’s Health Department Administrator calls his Communicable Disease Division Manager of the health department to report that “The planning for the pre-event smallpox vaccination clinic must be kicked into high gear. Our site may be chosen as a regional site for 6 counties”. If so, the plan will need to be completed in this month”.

Dec. 05, 2002, 7:14 AM: Passion County Health Department Administrator forwards the email of Dec. 02, 2002 from Nevada State Health Department to the Communicable Disease Division Manager, who is developing the county’s regional plan.

Dec. 05, 2002, 8:00 AM: A meeting of the Smallpox Response Planning Committee is called to discuss the new pre-event planning focus. The new focus is on vaccinating “first responders”. Passion County Health Department still does not have confirmation of whether they will be the regional site. The group has difficulty scaling the plan back from 180,000 persons to be vaccinated in an emergency situation to less than 6,500. There is still no guidance. No information is available to explain: 1) Who are first responders? 2) How many counties will be included? 3) How much time will be available to provide the vaccinations? 4) What liability protections are in place for vaccinators, employers, inadvertent inoculators? 5) Will families get the vaccination as well? 6) Can a person work with pregnant women or immunocompromised persons following vaccination? 7) Initial recommendations suggested that vaccine recipients go on work furlough for up to one month, until their scab fell off from their vaccination site. Is this still true? If not, “why”? What has changed? 8) Who will pay for the time off of work for people who suffer adverse reactions? 9) Who will pay for the costs associated with the clinic? 10) Who will pay for the special bandages that are needed for staff working directly with the public? The meeting ended with many questions unanswered and irritated group members. There was a consensus that the planning was moving too quickly.

Dec. 05, 2002, 11:00 AM: Communicable Disease Division Manager attends the CDC downlink of “Smallpox Preparedness Satellite Program”. Six additional staff persons from Passion County Health Department also attend.

Dec. 05, 2002, 2:45 PM: Communicable Disease Division Manager receives the email from the Passion County Health Department Administrator, which was sent at 7:14 AM.

Dec. 05, 2002, 4:09 PM: An email is sent to Nevada State Health Officials from the Association of State and Territorial Health Officials (ASTHO) stating that “Health and Human Services has determined that January 24, 2003 is the current effective date for whatever liability protections are actually provided under the recently enacted Homeland Security bill. The Administration will seek urgent Congressional action on an amendment to move the date forward as soon as the congress convenes on January 6, 2003”.

Dec. 06, 2002 : A letter is sent on Dec. 05, 2002 to local hospitals from the Director of the Nevada State Health Department informing them that “The first phase of [the smallpox bioterrorism event] involves offering the smallpox vaccine to public health staff who would be initially investigating and responding to a smallpox outbreak and healthcare workers who would be treating the first cases. This first part of the initiative is to start on December 16, 2002 and be completed in 30 days. Vaccinating first responders would be part of a later phase two”. It also stated, “Because of the tight time frame for completing this phase of the

initiative, we are asking every hospital to submit a plan of participation to the Nevada State Health Department by the close of business day on Dec. 13, 2002.

Dec. 06, 2002, 4:18 PM: An email with an attached press release is sent from the Nevada Health Department to all local health departments. It is stated that the press release will be released on the following Monday.

Dec. 09, 2002, 11:00 AM: A press conference is held in Carson City to announce Nevada's smallpox plan.

Dec. 09, 2002, 11:30 AM: Staff from Passion County Health Department hand-deliver the informational packets to all of the other local health departments in the county's region. Each local health department is asked to distribute the plans to their local hospitals. The informational packets contain handouts from the CDC website that the Communicable Disease Division Manager felt were important to helping health department and hospital staff make an informed decision about receiving the vaccination. The packets also contained a sign-up sheet for those persons interested in receiving the vaccine. Health departments and hospitals were asked to fax the information back to the Passion County Health Department by 4:00 on Dec. 12, 2002. The goal of the packets was to screen out persons with contraindications. This was done so a more accurate count of persons to be vaccinated could be used in the planning.

Dec. 09, 2002, 12:10 PM: The local TV station contacts the Communicable Disease Division Manager who declines comment & refers all inquiries to Passion County's Health Department Administrator.

Dec. 09, 2002, 1:49PM: Nevada State Health Department sends an email to all local health department Administrators informing them that their bioterrorism grant funds may be redirected to assist with costs associated with the pre-event smallpox vaccination clinics.

Dec. 09, 2002, 2:34 PM: Passion County Health Department Administrator receives an email from the Nevada Regional Health Officer stating that the subject of the trainings on Dec. 16, 2002 has been changed. The email also states that "regarding the smallpox inoculation plans due on the 13th: possibly yet today, a memo will be sent out by our department that is a checklist outlining what is needed to complete the plans".

Dec. 09, 2002, 3:00 PM: Local newspaper prints a story about local and state smallpox vaccination plans. One particularly misleading quote from Passion County's Health Department Administrator was printed when asked if he was to receive the vaccination, "I have not yet decided whether I will get the vaccine myself and I am not certain how many of my staff members will agree to the shot".

Dec. 10, 2002, 8:03 AM: Passion County Health Department Administrator forwards the above-mentioned email to the Communicable Disease Division Manager.

Dec. 10, 2002, 8:00 AM: Smallpox Response Planning Committee Meeting. The informational packets are distributed to all at the meeting for distribution to their staff prior to phase 2. The tone of the meeting is very adversarial. There are many, many questions directed at Passion County Health Department, which must go unanswered. The representatives from the Police, Fire Department, Emergency Services Disaster Agency, and local hospital are very irritated with the constant changes, lack of information, and the article that ran in the previous night's newspaper. They feel that all of the conflicting information is making them look uninformed to their organizations. There is a great deal of venting about the Nevada health department and the Centers for Disease Control and Prevention. Passion County Health Department is spared any blatant direct accusations of incompetence, but the tension remained in the air.

At the end of the meeting the representative from the hospital stated that she was going to advise her administrator not to participate in the pre-event vaccination. The representative from the police department kept getting the pre-event plan and the emergency plan confused. He wanted to "practice" the clinic. He also wanted all of the vaccinations to be given on one day. It was very difficult to convince the emergency planners that a pre-event clinic would not be that much different from a typical clinic that the health department does all of the time. The meeting ended with no plans for any future meetings. The Communicable Disease Division Manager stated that Passion County Health Department could submit the requisite plan without any further input from the planning body.

Dec. 10, 2002, 8:03 AM: Passion County Health Department Administrator sends an email to the local health departments within Passion County's region. The email states, "As well as I can tell now, our health department will be organizing and sponsoring smallpox vaccinations for phase 1 recruits in our region. As of Monday, I was told by the Nevada health department that the phase 1 vaccinations would probably not start until January 6, 2003, primarily because of unresolved liability issues".

Dec. 10, 2002: Nevada State Health Department sends a four-page letter with guidance on writing and submitting the regional plan. This letter is the first confirmation that Passion County Health Department has been chosen as the regional vaccination site.

Dec. 11, 2002, 1:00 PM: Communicable Disease Division Manager receives an email from the local hospital representative. She states, "I am not going to be able to distribute the packets to other hospitals or providers".

Dec. 11, 2002, 1:30 PM: Communicable Disease Division Manager emails the informational packet to the other local hospital.

Dec. 11, 2002, 4:00 PM: Passion County Health Department Administrator makes the Communicable Disease Division Manager the point-of-contact for all incoming calls.

Dec. 12, 2002: Faxes from persons interested in receiving the vaccination arrive throughout the day at Passion County Health Department. The development of the plan is interrupted numerous times from calls from the public. Such calls included: 1) Why can't my children & I receive the vaccine if we want it? 2) What do you mean I do not still have immunity? When I received the smallpox vaccination as a child I thought it would provide lifelong immunity 3) I read on AOL that you are not even giving smallpox vaccinations. You are actually inserting microchips under our skin so the government can track us.

Dec. 12, 2002, 4:00 PM: Deadline for participating health departments and hospitals within Passion County region to turn in their estimates of the numbers of persons who will be requesting the smallpox vaccinations. About half of the agencies respond to Passion County Health Department.

Dec 13, 2002: Work continues on the pre-event plan. Arrangements have to be made to dispose of the medical waste generated at a clinic site that is not the health department. The clinic site is changed from a health department building, which is under construction, to a local church, and back after the local church decides not to participate due to unanswered questions. The public health department building is still only tentative as there is no occupancy permit at the date the application was submitted.

Dec. 13, 2002, 1:59 AM: An email arrives at Passion County Health Department from a local hospital stating that they will participate, but they do not yet know how many people they may be sending for vaccination.

Dec. 13, 2002, 2:28 PM: Nevada State Health Department forwards remarks made by the CDC's Director regarding smallpox.

Dec. 13, 2002, 2:55 PM: An email arrives from a local health department in the region listing the numbers of persons who will be participating from their agency.

Dec. 13, 2002, 2:56 PM: An email is received from a local hospital stating that they will not be participating in the pre-event vaccination. The hospital director says, "As the program becomes better organized, we will move forward with a proactive rather than reactive position".

Dec. 13, 2002, 3:03 PM: Another hospital in the region sends their estimated numbers by email.

Dec. 13, 2002, 3:34 PM: Another local hospital submits their estimated numbers via email.

Dec. 13, 2002, 3:31 PM: Nevada State Health Department forwards a CDC Health Update of the president's smallpox plan for the nation.

Dec. 13, 2002, 3:40 PM: The National Association of County and City Health Officials (NACCHO) send an email with a link to the President's announcement of the smallpox plan. The president released his plan at 2:15 PM on this date.

Dec. 13, 2002, 3:45 PM: The Communicable Disease Division Manager finishes the pre-event smallpox vaccination plan and forwards it to the Passion County Health Department Administrator.

Dec. 13, 2002, 5:07 PM: Passion County Health Department Administrator submits an electronic copy of the Passion County Regional Pre-Event Smallpox Vaccination Plan to the Nevada State Health Department.

To date there has been no feedback on the plan that was submitted.

Several questions remain unanswered.

Conclusion

In the event of a smallpox attack, it is essential that an adequate number of “first responders” be vaccinated. This policy development process did not result in an adequate number of “first responders” volunteering to be vaccinated. There was insufficient time for the public, the public health providers, emergency personnel and other stakeholders to become educated and build consensus on the policy. There was confusion about decision-making authority, the actual policy, and not enough communication in all directions. As stakeholders may not have worked together prior to these meetings, particularly under the leadership of public health, this factor only contributed to the strain of facilitating the plan’s development on such an abbreviated schedule. Trust and buy-in was not achieved.

Core Functions of Public Health		
Core Function	Practices	Leadership Activities
Policy Development	4. Advocate for public health, build constituencies and identify resources in the community. 5. Set priorities among health needs 6. Develop plans and policies to address priority health needs.	Build coalitions, empower others. Clarify values, create vision, tie vision to mission Organize goals and objectives, translate goals into action

STUDY GUIDE
for

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1. Why do health professionals receive vaccine priority over general population?
2. Who/what will determine who gets vaccination priority?
3. Who is defined as a first responder? MD and RN's only? Or other licensed health workers?
4. What is the plan for distribution of vaccine?
5. Are all public health professionals encouraged to become vaccinated ASAP?
6. Will families of these public health professionals be vaccinated as well?
7. Why was the "Communicable Disease Division Manager" placed in charge of this plan?
8. What risk assessments have been/will be done to determine vaccine recipients?
9. How will materials for this be funded?
10. Post-vaccination, how will data be collected on adverse reactions?
11. Have coalitions been developed with local hospitals to treat those with adverse reactions?