Smallpox Vaccination Program - California

Country: USA
Partner Institute: Institute for Global Health (IGH), University of California Berkeley/San Francisco
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Health Policy Issues: Others, HR Training/Capacities

Current Process Stages

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1. Abstract

The campaign to vaccinate healthcare workers against smallpox continues to struggle in California. Opponents of the campaign are diverse, and cite concerns over the vaccine’s safety and financial risk to adversely affected vaccinated workers. Federal legislation in April established a fund to compensate vaccinated workers who suffered adverse effects, and the outbreak of monkey pox also elevated the perception of risk. However, vaccination rates continue to fall well short of targets.

2. Purpose of health policy or idea

Introduction

Led by California’s Department of Health Services and supported by other California health officials, California is implementing the federal government’s smallpox vaccination program. In the first survey round we documented California’s role in the initiation of the program, the issues that were controversial and the early response rate of health providers.

In the period of time covered by this second survey, California has continued its efforts to implement the smallpox vaccination program. This supplemental survey details the efforts and controversies that have recently occurred and describes how they are affecting California’s ability to implement the program.

Current Situation

The campaign to vaccinate healthcare workers against smallpox - so that they can step forward to help care for people if there is a smallpox outbreak - continues to struggle in California.

Following is a chronological summary of the state-wide activities surrounding smallpox during the six month period from March - August 2003. (Some of this information is excerpted from a timeline published by the California Department of Health Services.)

December 2002 - California submitted its plan for vaccinating healthcare professionals and began training sessions for vaccination providers.
January 2003 - California receives smallpox vaccine from CDC. Los Angeles County begins vaccinations under separate arrangement with the CDC.

February 2003 - California's Department of Health Services (CDHS) publishes list of smallpox vaccine contraindications and adds one to the CDC's: having an infant under one year old in the household. CDHS ships doses to local health departments. State Health Director Bonta gets vaccinated.

- At this point only 432 California health workers have been vaccinated. The reason for the low number was that many health care workers did not volunteer. In fact, there were organized campaigns by large labor unions - such as the California Nurses Association and Service Employees International Union - to discourage their members from getting the vaccination. The main reason for their resistance was the fact that the federal government had not created a fund to compensate workers who might become ill or miss work due to problems associated with the vaccine.

- In Southern California, Los Angeles County, which submitted its own plan requesting 9,200 doses, also faced low volunteer numbers. In fact, as of February 2003, 15 hospitals had opted out of the program. Furthermore, at that point the county had nine, of an eligible 83 hospitals, submit the names of employees who were willing to receive inoculations, and the total number of names was small.

- In Northern California, San Francisco General Hospital (the city's main public hospital) virtually barred its employees from getting the vaccine because of concerns over patient safety.

March 2003 - Secretary of the Department of Health and Human Services (DHHS) proposes vaccination compensation program for people injured as a result of being vaccinated. Compensation plan has to be approved by Congress.

California Department of Health Services (CDHS) continues shipping doses and mailing educational materials.

- March 25, 2003: CDC takes "precautionary step" and temporarily adds heart disease as a disqualifying condition and begins investigating any link between the vaccine and reports of heart problems in seven vaccinated healthcare workers. More significantly, three people - including two civilians - who had recently been vaccinated died of heart attacks. One person was a 55 year old National Guardsman, another was a 55 year old nurse with a history of high blood pressure, high cholesterol and smoking and the final death was a 57 year old nurse's aid.

- March 28, 2003: CDHS Director Bonta suspends all smallpox vaccinations in California until after April 7, 2003 to provide the CDC with time to investigate any link between the vaccine and heart problems.

- March 31, 2003: CDC accepts recommendation from the Advisory Committee on Immunization Practices (ACIP) that persons with heart diseases (with or without symptoms) and people who have three or more major cardiac risk factors (hypertension, diabetes, high cholesterol and smoking) be excluded from the vaccination program.

April 2003 - As of early April, 1,282 Californians had received the vaccine. (Nationwide 26,000 had been vaccinated.)

- April 7, 2003: **CDHS restarts program with new exclusion** for people with heart conditions per the CDC.

- April 11, 2003: Congress and the White House **approve a smallpox vaccination compensation program** to provide benefits to public health and medical responders who are injured as a result of the vaccine.
May 2003 - Secretary of DHHS announces an additional allocation of funds to states for the vaccination program.

June 2003 - **Monkeypox surfaces** in Ohio and health officials recommend that anyone handling or caring for humans or animals infected with monkeypox receive a smallpox vaccination as protection.

- CDC’s Advisory Committee on Immunization Practices (ACIP) adopts a resolution saying that the second phase of the vaccination program should not begin because the full risks associated with heart problems are unknown. The CDC’s Director chose to proceed against the committee’s recommendation saying that they "respect the ACIP perspective, but we also recognize that we still have work to do". The second phase aims to inoculate 10 million first responders.

July 2003 - According to newspaper reports, only about one-third (or 1,847) of the 6,400 doses prepared in California have been used.

- While California state health officials say they will continue the campaign their counterparts in the Los Angeles County Health Department are discontinuing the campaign.

August 2003 - The Institute of Medicine released a report recommending that when the vaccine is made available to the general public it only be given to people who are in clinical studies or other "carefully structured settings".

- According to a *New York Times* article, the IOM said the vaccine is "too dangerous" and the "risk of an outbreak is too small to justify wider use."

**Why the slow uptake in California and across the Nation?**

The number of health workers vaccinated in California is small - only one-third of the doses originally designated for use have been given - and while the campaign will continue on the state level, Los Angeles County health officials are considering their campaign over. (New York state and Ohio also consider their campaigns over.)

Nationwide, health professionals are unsure about the risks associated with the vaccine and recent media stories of illness and death soon after vaccination have stymied the vaccination campaign. The government has tried to quell fears about the safety and potential side-effects with education campaigns and a compensation program. In fact, according to a *Washington Post* article, "After months of pressure, the administration acquiesced to demands from unions, hospitals and public health departments in the hope that providing financial protection for the nation’s front line against bioterrorism would entice skeptical health care workers to be immunized."

However, there are still concerns.

Originally health officials disqualified about 1 in 3 Americans as candidates for the vaccine - people with immune system problems, a history of eczema or pregnant women are all disqualified. However, last Spring, after a number of people experienced health problems and three died shortly after being vaccinated, health officials expanded the disqualifying conditions to include anyone with a heart condition or risk factors for a heart condition.

Clear evidence of a link between the death and the other people’s health problems has not been found but, obviously, health officials want to protect the public and preserve their trust.

**Expansion of the Program to General Public**

While the Institute of Medicine is widely respected, their August 2003 recommendations are only recommendations and it is possible that they will be ignored or side-stepped by proponents of wider scale vaccinations much as the CDC ignored the recommendations of it’s own Advisory Committee on Immunization Practices by commencing the second
phase of the vaccination program.

However, in California, it is quite likely that there will be resistance among general public for mainly because of the perceived decrease in risk of attack and the perceived dangers of the vaccine. If a safer vaccine is developed - there are already efforts underway - then perhaps the public will respond more favorably.

Main objectives
To vaccinate health care workers against smallpox

3. Characteristics of this policy

| Degree of Innovation | traditional | innovative |
| Degree of Controversy | consensual | highly controversial |
| Structural or Systemic Impact | marginal | fundamental |
| Public Visibility | very low | very high |
| Transferability | strongly system-dependent | system-neutral |

4. Political and economic background

The smallpox vaccination program represented a substantial change in government direction and was a reaction to the threat of terrorism with biological agents. There had not been organized smallpox vaccinations in decades. California's response - as directed by the California Department of Health Services - with a few exceptions, followed the guidelines of the CDC. The exceptions are notable because they reveal the difficult balance the CDHS tries to maintain as a supporter of nationwide efforts generally and a protector of California's health specifically.

5. Purpose and process analysis

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Origins of health policy idea
No new update.

Stakeholder positions
Following is an overview of the main stakeholders and their positions in the last six month period.

- California's State and Local Health Departments - California's Department of Health Services has led the efforts
and has not received the local support they had hoped for. CDHS, like the CDC, has borne much of the blame for any problems. That said, CDHS has broken ranks with the CDC when it feels it needs to in order to protect the health of Californians. Furthermore, while the vaccination program is still active one could argue that the CDHS is not putting the energy into it as it once did.

- The Bush Administration - President Bush and his administration are strong proponents for the vaccination program. However, since announcing the program, the administration seems to have positioned itself to skirt much of the implementation criticism by putting DHHS and the CDC out as public representatives.

- The Federal Government - Federal government agencies such as the CDC have been responsible for distributing the vaccines to the states and for sharing information about smallpox. The CDC has frustrated some groups who believe the agency is not taking a strong enough role and others who believe the agency is releasing confusing information. Indeed, the CDC has borne much of the criticism for any implementation problems or health problems. And, the CDC has also seen internal dissent over protocols such as when the CDC Director dismissed recommendations of the CDC's own committee (ACIP).

- California's Labor Unions - Labor unions such as the California Nurses Association (CNA) and Service Employees International Union (SEIU) have taken strong positions against the vaccination program by discouraging their members from getting vaccinated when there was no compensation fund to help workers who become ill or miss work. Now that there is a fund, there is still resistance. Some labor officials say the risk of a smallpox attack seems so low that it is not worth risking an adverse reaction. Furthermore, the CNA have said that the program represents a "massive diversion of public resources for badly needed health care towards a program that has, to this date, been demonstrated to be totally unnecessary."

- California's Hospital Administrators - Hospital Administrators are also making decisions about whether or not they recommend their employees get vaccinated. Many of their concerns rest on protecting their employees and their patients. For example, San Francisco General Hospital (the city's main public hospital) virtually barred its employees from getting the vaccine because of concerns over patient safety.

- California's Physicians and Healthcare Workers - The professionals responsible for caring for people if there is an attack have responded to the program in a variety of ways. Many have agreed to participate and be vaccinated. Many more are not agreeing - some out of concern for their health or for their patient's health and others because they believe the risk of attack is low and the vaccine risks high.

- General Public - The general public has followed this debate with much interest and there are many different points-of-view. Some believe the threat of a smallpox attack is real, some do not. Some believe the hazards of the vaccine are too great, other believe the risks of not getting vaccinated are greater. The main thing is that they are watching the outcomes of the military and healthcare worker vaccination programs and when problems arise - such as the deaths among vaccinated civilians with heart problems - their suspicion of the program's merits increase.

Influences in policy making and legislation

California's participation in the national vaccination program is part of a voluntary federal program that is not the result of legislation. However, establishing a fund to compensate workers who have adverse effects from the vaccine required federal legislation (passed in April 2003).

Legislative outcome

Adoption and implementation

All of the stakeholders described in 5.2 are involved in the adoption process for the smallpox vaccination program. The program, which was initiated by the Bush Administration, is being moderated by the federal and state governments. Because of the nature of the issue, the entire United States has a stake in the program - but not all states have been active in the adoption process. As mentioned, in California labor unions and some health and/or
hospital administrators have strongly opposed the program and have, as a result, slowed its adoption.

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**Monitoring and evaluation**

At the end of the smallpox vaccination program, the medical community will evaluate the success based on health outcomes and the policy community will evaluate the success based on the risk of attack. Together, these two communities are likely to present an approach that says if the risk of attack is high, the health risks are acceptable and if the risk of attack is low, the health risks are unacceptable.

Therefore, whether or not the smallpox vaccination program is deemed a success in California and across the Nation, depends on who is evaluating the success and that group's perspective on the risks associated with the virus and the possibility of a smallpox attack.

However, experts have already gone on the record with their thoughts on the success of the vaccination program. In a July 2003 *Pittsburgh Post-Gazette* article, the dean of the School of Public Health at the University of California, Los Angeles was quoted saying "the fact that the doses aren't being used is a marker of what's commonly recognized: that the vaccine campaign failed in meeting its original objective. I don't think [the campaign] was ever sufficiently well-justified to the medical and scientific communities that the risk of [smallpox] exposure was so great as to warrant such an aggressive approach."

Surely, the fits and starts experienced in California since the program began in December 2002 show that there have been points of evaluation throughout and that, at times, medical experts have briefly halted the program due to safety concerns. Each time a new safety concern is discovered the number of people who are willing (and eligible) to be vaccinated decreased - threatening the overall success of the initiative.

The CDC has announced they are ready to begin the next phase - vaccinating volunteers from the general public. Yet, in light of recent reports such as the August 2003 IOM report, it does not seem likely that many people will step forward to receive the vaccine.

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**6. Expected outcome**

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7. References

Reform formerly reported in

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