Kennedy School of Government
Case Program

C15-03-1709.0

When Prevention Can Kill: Minnesota and the Smallpox Vaccine Program

In early 2003, the Minnesota Department of Health (MDH) had implemented, on short notice, an ambitious program that deployed public health officials in the fight against terrorism. Despite the misgivings of some key MDH officials, Minnesota had gone ahead with Phase 1 of a federal smallpox vaccine program and inoculated a core group of some 1,400 health care workers, who could vaccinate the general public in the event of a terrorist attack that used smallpox as a weapon.

By mid-March, despite substantial obstacles, Phase 1 was essentially over—and the chief emotion at MDH was relief. The all-out push had exhausted MDH and its local health care partners. Phase 1 had also proven expensive in terms of time, effort and money. MDH was looking forward to a hiatus during which it could evaluate the effectiveness of Phase 1. MDH did not yet know, for example, whether Phase 1 had even achieved the goal of medical preparedness for a smallpox attack.

But as Phase 1 drew to a close, pressure mounted to move directly into Phase 2—vaccination of "first responders," meaning police, fire and emergency personnel. In Minnesota, that could mean upwards of 200,000 vaccinations. The federal government had announced that states were free to move to Phase 2 at will. The issue came to a head for MDH when the sheriff of Ramsey County, seat of the state capital St. Paul, demanded that his public safety officials be vaccinated without delay. Failure to do so, he charged, would demonstrate that MDH would protect its own but not those who protected the public.

This case was written by Kirsten Lundberg for Arnold M. Howitt, Director of the Executive Session on Domestic Preparedness, Kennedy School of Government. Funding was provided by the Volpe National Transportation Systems Center, US Department of Transportation, with additional assistance from the Robert Wood Johnson Foundation. (0803)

Minnesota Assistant Health Commissioner Aggie Leitheiser was worried about how those in her department who had handled Phase 1 would respond to the sheriff's request. Virtually no one at MDH wanted to embark yet on Phase 2. While Leitheiser respected the professional judgment of the doctors and public health experts at MDH, she could also see the sheriff's point of view. Leitheiser called a meeting for March 13, 2003, of top MDH officials to discuss the Ramsey County situation. Implicit in the question of how to respond to the sheriff were larger issues. MDH needed to ask itself what constituted preparedness? How many vaccinated people was enough? What job categories were essential? How would MDH define success for the smallpox vaccine program?

Smallpox Vaccine Policy—Background

The smallpox vaccine program which Minnesota had implemented had its roots in the events of September 11, 2001. After the suicide hijackings that day, and the anthrax attacks of October 2001, the federal government stepped up efforts to prevent terrorist use of biological weapons. The Bush Administration suspected that terrorists, or hostile states like Iraq, might already control stocks of smallpox—a highly contagious disease which the World Health Organization declared eradicated in 1980 but examples of which were preserved in laboratories in the US and Russia. The US general population was vulnerable to smallpox. Routine vaccinations had stopped in the US in 1972.[1] Without vaccination, the disease killed one-third of those infected.

In November 2001, the Centers for Disease Control and Prevention (CDC)—which is a branch of the Department of Health and Human Services (HHS)—published a *Smallpox Response Plan and Guidelines*, which it updated in January and again in September 2002. That document laid out what various agencies should do in the event of a smallpox attack. Essentially, it called for mass vaccination against the disease. Even before September 11th, HHS had begun to build up its stockpile of vaccine; this process accelerated in October 2001. By the end of 2002 or early 2003, HHS expected to have available over 285 million doses.[2]

ACIP Report. Meanwhile, a debate began within government about whether the US should inoculate—in anticipation of a smallpox attack—some number of healthcare workers who could vaccinate everybody else if the need arose. This was known as a "pre-event" vaccine program because individuals would be vaccinated even though there had been no outbreak of disease. Under existing US policy, only scientists and laboratory workers testing smallpox-related

[1] The last known case occurred in 1977 in Africa.

[2] The government still had 15 million doses frozen. It was buying 209 million doses from the Cambridge, England, firm of Acambis. The drug company Aventis Pasteur additionally donated 80 million doses it had kept frozen since 1958, which the government said it would keep as an emergency supply. Source: Lawrence K. Altman, "Smallpox vaccinations urged for health care workers," *New York Times*, June 7, 2002, p.A24 and William J. Broad, "US guide for mass smallpox vaccinations," *New York Times*, September 24, 2002, p.A19.

viruses received vaccines. Since 1983, only 11,000 Americans had been vaccinated against smallpox.[3]

Some in the healthcare community advocated immunizing *everyone* in advance of an outbreak because they felt the traditional "ring vaccination" control and containment model would not work. Under that model, doctors isolated the patient and vaccinated those who had had direct contact with him/her. William J. Bicknell, a Boston University School of Public Health physician and former Massachusetts health commissioner, objected that "ring containment in a terrorist situation has been thoroughly discredited… and that has not been recognized by CDC."[4] He pointed to Yale University research which predicted that 1,000 infections would lead to nearly 100,000 deaths in three months if handled by ring containment, but fewer than 1,000 deaths if mass vaccination took place. Yale public health specialist Edward H. Kaplan agreed, commenting that "[u]nless the initial attack is very small and the infectiousness of the agent is quite mild, ring vaccination is not going to do much good."[5]

In search of an expert opinion, the government in the spring of 2002 asked a prestigious advisory group to consider whether a pre-event vaccine program made sense and if so, on what scale. On June 20, 2002, the Advisory Committee on Immunization Practices (ACIP)—which routinely advises CDC and HHS—recommended that a small number of volunteer healthcare and law enforcement workers in each state be vaccinated against smallpox.[6] This core cadre of "smallpox response teams" would provide initial care and vaccinations in the event of a smallpox outbreak.[7] At least one hospital per state would be designated as a referral center for smallpox. The ACIP report gave no official target number, but individual committee members estimated that 15,000 to 20,000 people nationwide would suffice. The option was the most limited of several the panel considered; it outright rejected the proposal to inoculate every American.[8]

In reaching its decision, ACIP had to weigh the advantages of having an immune group, combined with the likelihood of an attack using smallpox, against the risks posed by the vaccine itself. The difficulty was that, because smallpox had been eradicated, the risk of getting smallpox was actually zero until the moment that an attack occurred. So the risk of an attack was part of ACIP's equation. But so far, the government—to protect intelligence sources or because it did not know—had provided no firm evidence of a planned attack. The vaccine, on the other hand—while safe for most people—carried the highest risks of any vaccine in use.

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3 William J. Broad, "US to vaccinate 500,000 workers against smallpox," *New York Times*, July 7, 2002, p.A1.

4 David Brown, "Limited smallpox vaccine use eyed," *Washington Post*, June 21, 2002, p.A1.

5 Broad, "US to vaccinate 500,000 workers against smallpox."

6 The National Vaccine Advisory Committee also deliberated over vaccine policy, but the ACIP recommendations are the ones that drew the greatest public attention.

7 A typical team would include a doctor, nurse, public health adviser, epidemiologist, disease investigator, diagnostic laboratory scientist, vaccinator and security and law enforcement workers. Source: Lawrence K. Altman, "Traces of Terror: the bioterror threat," *New York Times*, June 21, 2002, p.A16.

8 Brown, "Limited smallpox vaccine use eyed."

Vaccine Drawbacks. Made from the smallpox-related *vaccinia* virus, or cowpox, the smallpox vaccine worked because the body considered it identical to smallpox and manufactured antibodies to both.[9] But the vaccine could cause serious complications. Fully 30 percent of Americans were advised not to take the vaccine because they suffered from conditions—such as eczema or compromised immune systems—which increased their risk of complications.[10] Of the remaining 70 percent, studies from the 1960s indicated that 14 to 52 people per million would suffer serious reactions such as encephalitis (brain inflammation) and blindness, while another 50 to 900 would suffer complications like fever, sore arms, swollen lymph nodes and other aches. One or two per million would die. Interestingly, in the fall of 2001, CDC vaccinated some 200 staff members against smallpox, but canceled plans to vaccinate more once they saw the severity of the reactions.[11]

The smallpox vaccine was classified as "investigational" or experimental because, while it had been widely used in the past, the standards under which it was made were no longer current. Anyone receiving the vaccine had to sign in advance a consent form of the sort typically used in drug trials.[12] Not only did the vaccine itself cause reactions, but for 19 days after the vaccination, the *vaccinia* infection could spread (in a process known as "shedding") from those who had just been vaccinated. Proper bandaging, and a careful change of dressings, could prevent this.

In response to the ACIP recommendation, HHS Secretary Thompson said he would "now review the recommendation with experts … as the Administration works toward a policy on the smallpox vaccine."[13] He added: "We plan to move as expeditiously as possible so that we have a policy in place as more vaccine becomes available later this year."[14] HHS had never rejected or significantly modified an ACIP recommendation.[15] The ACIP chair and Dr. Julie L. Gerberding, acting deputy director of CDC, said it would take several months to carry out the ACIP recommendations if they were adopted.[16]

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9 The vaccine was made from pustules that formed on the bellies of calves infected with vaccina. Scientists extracted fluid containing the vaccine from the pustules, cleaned it up, treated it with antibiotics and froze it. Source: Josephine Marcotty, "Smallpox Vaccinations; Ready or not," *Minneapolis Star Tribune*, January 27, 2003, p.1A.

10 Studies showed that among eczema sufferers, the rate of complications could be one per 100,000 vaccinations, higher than the risk of paralysis from polio vaccine—which the government halted due to the high risk. Source: Lawrence K. Altman, "Action delayed on vaccination advice," *New York Times*, August 25, 2002, p.22. On the other hand, in the event of an outbreak of smallpox, these individuals would have been vaccinated without hesitation.

11 Altman, "Action delayed on vaccination advice."

12 The government did have an antidote to the more dangerous side effects, called vaccinia immune globulin (VIG).

13 Brown, "Limited smallpox vaccine use eyed."

14 Lawrence K. Altman, "Panel rejects immunizing all against a smallpox outbreak," *New York Times*, June 21, 2002, p.A16.

15 Altman, "Action delayed on vaccination advice."

16 Lawrence K. Altman, "Panel rejects immunizing all against a smallpox outbreak," *New York Times*, June 21, 2002, p.A16.

Why smallpox? Why now?

As it was, it took nearly half a year for HHS and CDC to decide on the structural design of a pre-event smallpox vaccine program. During that time, state public health departments—frustrated by the lack of definite instructions but fearful of being unprepared—struggled to stay on top of the situation. As early as July 7, 2002, reports began to surface that the government intended to vaccinate not 15,000-20,000, but 500,000 public health and emergency workers. HHS Acting Assistant Secretary for Emergency Preparedness Jerome Hauer predicted that vaccinations could start within eight weeks.[17] But then nothing happened. "It's much more complicated than one might imagine," said Dr. Donald A. Henderson, chairman of the HHS Secretary's Council on Public Health Preparedness.[18] Those who would inoculate others needed training. The newly inoculated could be out of work for up to 10 days. There was also debate over whether to require an HIV or pregnancy test for all who wanted the vaccine, due to the known danger it posed to expectant mothers and people with compromised immune systems. Other questions included:

- Who would have legal liability if the vaccine produced an adverse reaction? The doctors/nurses who administered it? The manufacturer?
- Who would pay those vaccinated for time lost from work?
- Who would pay to screen those who wanted to be vaccinated?

Pros and cons. Inside and outside the Administration, supporters and opponents of a pre-event vaccine program took to the op-ed pages and the airwaves with their views. The chief argument of those who opposed it was that the government had failed to identify any specific threat. They speculated that the Bush Administration was using the smallpox vaccine for political purposes. The Administration had embarked on a campaign against Iraq—accusing it of harboring terrorists and building weapons of mass destruction—that seemed likely to end in a war. US public support of a war was, however, far from ensured. The critics wondered out loud whether the smallpox vaccine program was meant to stir up public anxiety and thus support for the war?

Vaccine supporters accepted the Administration claim that terrorists and hostile states, such as Iraq, were capable of manufacturing and using smallpox in a biological attack. They felt it was only a matter of time before the US would have to confront the consequences of such an attack. Prudence alone, they argued, dictated a pre-event vaccine program.

On the medical front, opponents pointed out that, because the vaccine was effective up to four days after exposure, the government could wait to vaccinate until after a smallpox outbreak.

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[17] Ceci Connolly, "Smallpox vaccine program readied," *Washington Post*, July 8, 2002, p.A1.

[18] Ceci Connolly, "Smallpox vaccine program readied." Henderson had led the worldwide smallpox eradication effort in the 1970s.

Supporters argued that because incubation lasted an average 12 days, individuals might not realize they had been exposed. Moreover "weaponized" smallpox, such as terrorists might develop, could spread much faster than the standard virus. Multiple, simultaneous infections could dwarf the ability of public health authorities to conduct a post-facto vaccination program.

Minnesota August Draft

Public health officials in Minnesota followed—and participated in—this debate closely. By August 2002, they concluded that some version of the ACIP recommendations would be adopted and that they had better prepare. Responsibility for vaccinations at MDH rested with the Infectious Disease Epidemiology, Prevention and Control Division, headed by State Epidemiologist Dr. Harry Hull. Within the division were two sections which could logically manage a smallpox vaccine program. The Acute Disease Investigation and Control Section had already been working on smallpox as part of a broader bioterrorism prevention program. The Immunization, Tuberculosis and International Health Section handled vaccinations.[19] Richard Danila was the head of Acute Disease (and deputy state epidemiologist), while Kristen Ehresmann directed the Immunization Section.

In an effort to stay ahead of the curve, Ehresmann, Danila and a few colleagues drew up a preliminary pre-event smallpox vaccination plan for Minnesota. Dated August 30, the draft plan presented four scenarios:

- obtain vaccine supplies but vaccinate no one
- vaccinate some 1,000 medical personnel as per ACIP, e.g., smallpox response teams, a laboratory response team, regional patient care teams, plus a few security staff
- vaccinate some 100,000 health care personnel, e.g., public health staff, emergency management staff, medical teams, and others such as law enforcement, public utility operators
- vaccinate 1 million people, e.g., all possible contributors to a smallpox response[20]

The draft plan noted that, at the moment, no smallpox vaccine was commercially available. It also raised a number of MDH concerns. They included: Is Minnesota *required* to vaccinate? Does MDH have a policy regarding workmen's compensation after vaccination? Who would meet with staff to explain vaccination options? Who would indemnify the state for associated costs? How

[19] Two other sections had little role to play: the Epidemiology Field Services Section and the AIDS/STD Prevention Services Section.

[20] Minnesota has a population of some five million.

would MDH monitor whether each vaccine "took" (was working) or not? Would members of response teams receive extra compensation?

The plan circulated within MDH on a limited basis but, because there was no movement at the federal level, MDH took no further steps for the time being.

Gathering Speed

In September, debate continued to simmer on the advisability of a pre-event vaccine program. According to press reports, Vice President Dick Cheney was said to want rapid, universal vaccination while HHS Secretary Thompson preferred a voluntary program that would wait at least two years for an improved vaccine.[21] Thompson's advisor Dr. Henderson argued for more limited vaccinations.[22] "If you look at the vice president's office, they're thinking strategic [policy], not public health," one insider told a reporter. Thompson's concern, he continued, was that "if something bad happens [as a result of smallpox vaccine], the public is not going to be blaming Dick Cheney, they're going to be blaming Tommy Thompson."[23]

But by October, there were signs that discussion had moved on to the more practical matters of liability, compensation and logistics. On October 4, HHS gave the states a heads-up that some kind of pre-event vaccine program was in the offing. In a conference call, HHS urged state public health officials to begin planning—while they waited for a policy recommendation from Secretary Thompson—how to do pre-event vaccinations. Under current consideration, HHS told the states, was a three-stage program: first up to 500,000 front-line health care workers; then some 10 million first responders; and finally the general public. When and if a public announcement was made, HHS said, states would have 60 days to prepare for Phase 1 and 90 days to implement it. The conference call, says MDH Immunization Section Leader Ehresmann, "was a wakeup call." She realized that the job of coordinating MDH's response was likely to be hers, so "I took the approach of I better get going with this, because I knew it was going to fall on me."[24]

Ehresmann and her colleagues had an additional source of information on federal intentions. Dr. Michael Osterholm had been former Minnesota state epidemiologist and now served both as director of the Center for Infectious Disease Research and Policy at the University of Minnesota and on the HHS Secretary's Council on Public Health Preparedness. Osterholm, without violating any confidences, was telling Minnesota state officials that the threat of a smallpox attack was real. Recalls Robert Einweck, director of the Office of Emergency

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[21] Barton Gellman, "4 nations thought to possess smallpox," *Washington Post*, November 5, 2002, p.A1.

[22] Ceci Connolly and Dana Millbank, "US revives smallpox shot," *Washington Post*, December 14, 2002, p.A1.

[23] Ibid.

[24] Author's interview with Kristen Ehresmann in Minneapolis, MN, on March 27, 2003. All further quotes from Ehresmann, unless otherwise attributed, are from this interview.

Preparedness (OEP) within MDH: "He said this is a moving train, and we'd better start catching up with it. We took it very, very seriously [thinking] it could happen as soon as next month."[25]

ACIP Again. Further confirmation that a decision was approaching came on October 16, 2002, when ACIP revised its earlier recommendation and endorsed the idea of immunizing 500,000 public health and hospital workers across the country. A committee member said the number of first-stage vaccinations was revised upward because it became apparent that individual hospitals were reluctant to be designated as smallpox centers.[26] The solution was to ask any hospital with a "negative air pressure isolation room"—a room for respiratory patients constructed to prevent air inside from circulating outside—to form a smallpox care team.

The ACIP meeting also affirmed that the Administration was moving forward with plans for a second phase of vaccinations for up to 10 million first responders. ACIP voted down, however, a suggestion that the 10 million should be vaccinated immediately.[27] Dr. Paul A. Offit, head of the vaccine center at Children's Hospital of Philadelphia and the only member of ACIP to vote against the 500,000 proposal, said later that the Bush Administration did not pressure the panel but that "the sense was that the course was already set and we wouldn't make any difference."[28]

By late October, signs accumulated of a looming decision to launch a smallpox vaccine program. CDC guidelines to states on smallpox preparedness (Announcement 99051), issued on October 28, did not announce a pre-event vaccination program but did specifically mention the need to vaccinate response teams in anticipation of an outbreak of smallpox. At the same time, the Food and Drug Administration re-licensed the first 117 million doses of vaccine, removing another hurdle to a pre-event vaccine campaign.[29] With these developments, state public health officials from HHS Region V decided it was time they confer about the pending federal program.[30] The five states scheduled a meeting for October 30 in Chicago.

Region V Meeting. From Minnesota, Commissioner of Health Jan Malcolm went to the Chicago meeting, along with Ehresmann, a department lawyer and an MDH mass clinic planner.[31] Each state, remembers Ehresmann, "was questioning whether or not they could or should do vaccinations… There were liability issues. There were ethical issues." At the end of the meeting, the state officials presented HHS and CDC with a list of questions, what Ehresmann terms

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25 Author's interview with Robert Einweck, St. Paul, MN, March 26, 2003. All further quotes from Einweck, unless otherwise attributed, are from this interview.

26 David Brown, "Panel alters advice on smallpox shots," *Washington Post*, October 17, 2002, p.A3.

27 It also voted not to make AIDS or pregnancy tests mandatory for those to be vaccinated.

28 Marie McCullough, "So far, only 687 vaccinated for smallpox," *Pittsburgh Post-Gazette*, February 7, 2003, p.A1.

29 Ceci Connolly, "President reviving program to provide smallpox vaccine," *Washington Post*, December 12, 2002, p.A1.

30 Region V includes Minnesota, Michigan, Indiana, Wisconsin, Illinois and Ohio.

31 The other two were MDH legal counsel Steven Shakman and MDH planner Luanne McNichols.

"showstoppers—all the things that make us say we don't know if we can do this." They included: Who should be vaccinated pre-event and in what order of priority? Who would train the first-round vaccine givers? Who assumes liability—for the vaccine manufacturer, the vaccine givers, vaccinated persons who inadvertently infect others by "shedding" vaccine, and for hospitals where the vaccine is administered? Who compensates hospitals for the time personnel spent running vaccination clinics? Who pays compensation for vaccinated individuals who miss work or who become seriously ill?

Most of the Region V officials' questions had not been answered when, just three weeks later, the request for action plans arrived. On Friday, November 22, CDC instructed states to submit—by December 9—full-fledged plans for pre-event vaccinations of medical and public health smallpox response teams. CDC could not compel states to submit such plans; the agency's authority over state health departments was quite limited. CDC can send personnel to a state experiencing a disease outbreak, for example, only by invitation. But it did have the power of persuasion, and it owned the vaccine stocks. Any state that ordered vaccine from CDC thereby agreed to administer it.

Once the state plans were in hand and approved, the federal government would announce the program to the public. Not only would states have barely two weeks to prepare their plans, but the speed of implementation had been significantly increased since October. Instead of 90 days from the time of announcement, states should complete all vaccinations within 30 days.

Homeland Security Act. The CDC request came just before President George Bush signed into law, on Monday, November 25, the Homeland Security Act of 2002. The much-debated Act created a new Department of Homeland Security, combining 22 government agencies into one mammoth department. Bush nominated Homeland Security Adviser Tom Ridge as head of the new agency. One section of the Act laid to rest some of the concerns raised by the Region V states. Section 304 provided legal protection for smallpox vaccine manufacturers and anyone who administered the vaccine, including hospitals. To recover damages, anyone harmed by the vaccine would have to sue the federal government and prove negligence on the part of the accused. The Act made no mention, however, of compensation for those *taking* the vaccine who might as a result miss work or incur medical bills, nor of liability for secondary infections.

Minnesota Overdrive

The news that HHS wanted detailed pre-event smallpox vaccination plans from each state hit MDH hard. One issue was logistical—how would the state put together a comprehensive plan in little more than two weeks? Once the plan was set, how would it be implemented? What about the outstanding questions of liability and compensation? The other was ideological—how would those within the department who questioned the nation's need for and Administration's motivation for a vaccine program be able to work on it?

The CDC requests for information were considerable. It wanted to know who would manage the vaccine program, the timeline, the organization chart, how many public health and medical response teams were needed and what kind of experts would be included on each team, the number of participating hospitals, state policy on hospital responsibilities, clinic sites and times, how states would train vaccinators, the number of days and hours per clinic plus the number of personnel required to run them. It wanted to know how clinic staff would screen potential vaccines, as well as how they would monitor the after-effects of the vaccine.

States also had to guarantee the security of the vaccine itself because there was considerable fear that terrorists might capture the vaccine and infect people with *vaccinia*. CDC asked Minnesota and other states to provide contact numbers and places for delivery of the vaccine, to stipulate the number of required doses, and to devise a strategy for safeguarding the vaccine. It also asked them to establish data management and communications programs, plus a plan to report their progress on a semi-weekly basis (Mondays and Thursdays) to CDC.

Yes or No? Minnesota, before taking any further steps, asked the CDC whether its Scenario 1 of August was viable: to stockpile vaccine but not vaccinate anyone until after an outbreak. That, says State Epidemiologist Hull, "would have been my preferred plan."[32] But the answer was no. The CDC would provide vaccine only to states prepared to vaccinate.

So the question became: how to respond? At a meeting the same day the CDC request arrived, November 22, MDH staff raised multiple questions and concerns. The conversation continued on Monday, November 25, during a two-hour meeting called by Dr. Hull. As Ehresmann remembers: "There was a lot of dissension within our division as to whether or not we should do this." She adds:

> "People felt that in public health we're used to doing things that are pretty purely for the good. You've already established that the benefits outweigh the risks before you do it in a public health setting. We're just not used to contemplating a public health activity in which people may die, there may be negative consequences."

In a memo, Hull attempted to answer some of the more pressing staff questions. On how many people MDH would vaccinate, Hull indicated that the number would be up to 10,000. That number was arrived at rather imprecisely, just as the federal 500,000 number had been. CDC had multiplied 5,000 qualifying hospitals nationwide by 100 personnel per hospital to get a target number of 500,000 vaccinees across the country. Ehresmann and her colleagues similarly multiplied what they thought was the number of qualifying hospitals in Minnesota, 62, by 100 to

[32] Author's interview with Dr. Harry Hull, Minneapolis, MN, on March 25, 2003. All further quotes from Hull, unless otherwise attributed, are from this interview.

arrive at 6,200 hospital personnel to vaccinate.[33] To that, they added nine public health teams, one for each MDH region in the state, as well as a few security personnel to guard the vaccine and the clinics. That gave them a rough estimate of 10,000 potential vaccinations.

MDH staff also worried about liability issues, but Hull assured them that the Homeland Security Act would take care of that. Some staff feared that health workers might feel coerced to accept the vaccine. Hull tried to reassure them that the program was entirely voluntary. They asked about training materials (the CDC would provide some, MDH develop others), and about the timeline (depends on when the President announces a program, but Hull anticipated that MDH could be vaccinating health care workers by mid-December 2002).

Finally, Hull and the department grappled with the question of the purpose behind the vaccine program. Was it motivated exclusively by public health concerns, or were there political considerations? An Administration intelligence assessment made public in November which concluded that four nations—Russia, Iraq, France and North Korea—had covert stocks of smallpox did little to persuade the skeptical.[34]

"Several of us here," says MDH Acute Disease Section Leader Danila, "felt really strongly that this was merely a political ruse to support a war effort, rather than a public health preparedness effort."[35] Others at MDH, however, suspected that "there were people who were using objections to the smallpox vaccination program as a way of expressing their dissent from the decision to go to war." In his memo to staff, Hull said that "if the federal government announces that vaccination is necessary because of a threat to the country, MDH will not be in a position to say that the threat is not real… We have to accept that, for security reasons, we may never know all of the facts." At the same time, Hull expressed the hope of many that "the risk of a smallpox attack may be clarified with the announcement of the program." As Ehresmann puts it: "We wanted to have evidence of a credible threat."

The debate continued to percolate internally, but top MDH officials decided that, for practical purposes, the process of planning had to be considered separately from that of implementation. It was essential the state at least have a plan in place. So for the next two weeks, some 30 MDH staff worked overtime to complete a 48-page proposal plus appendixes which provided all the information CDC required.

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33 As Danila points out, the number 62 was a "guesstimate in the dark" of how many Minnesota hospitals had functioning negative pressure rooms. The actual number was 66—but not all those were able to contribute to the smallpox effort.

34 See Gellman, "4 nations thought to possess smallpox."

35 Author's interview with Dr. Richard Danila, Minneapolis, March 25, 2003. All further quotes from Danila, unless otherwise attributed, are from this interview.

Who Does What

MDH officials had first to map out what needed to be done, and then decide who should do it. The "what" was fairly clear-cut: MDH would ask for volunteers to join teams that would deploy in the event of a smallpox outbreak, and vaccinate them. There would be two kinds of smallpox response teams: public health and medical.[36] Public health teams would draw volunteers from state and local public health departments. In the event of an attack, these teams would have two jobs: vaccinate the public, and trace the contacts of smallpox patients (and vaccinate those contacts). Volunteers for the medical teams would come from hospitals. If there were a smallpox outbreak, these teams would provide 24-hour care for the patients.[37] To vaccinate team members, MDH would run two categories of clinics: public health clinics to vaccinate public health volunteers and a few public safety officials; and hospital clinics (located there for the convenience of hospital staff) to vaccinate medical workers. Public health doctors and nurses would administer the vaccinations at both kinds of clinics.

To make this happen, MDH needed managers. But deciding who was in charge of the smallpox vaccine program was not straightforward. On the one hand, MDH Section Chiefs Ehresmann (Immunization) and Danila (Acute Disease) had already taken responsibility for preliminary plans, participated in conference calls and attended meetings. On the other hand, in June 2002, the state had created an Office of Emergency Preparedness (OEP) as part of an anti-bioterror effort mandated and funded by the federal government. It was only logical that OEP take a lead role in the smallpox vaccine program. At least OEP, headed by Robert Einweck, was part of MDH. But, housed in an MDH building in St. Paul, OEP was not physically close to Ehresmann and Danila, who were in Minneapolis.[38] In terms of hierarchy, Einweck reported directly to Assistant Commissioner for Health Protection Aggie Leitheiser, while Ehresmann and Danila reported to Hull, who reported to Leitheiser.

In the end, the MDH plan proposed that both OEP and Infectious Diseases together run the smallpox vaccine program. Ehresmann was made Smallpox Vaccination Officer (SVO) with Danila as her back-up, but OEP stood at the top of the organization chart.[39] "We created this unbelievable work chart," says Danila. "What we learned is that when you put everybody in charge, nobody's in charge … It just gets quite complicated."

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36 This characterization is only for purposes of general description. Of course there were medical doctors and nurses on the public health teams, as well as hospital doctors well trained in public health.

37 Hospital teams could include emergency room staff, intensive care unit staff, medical subspecialists (dermatologists, anesthesiologists etc.), radiology technicians, respiratory therapists, and security personnel.

38 Minnesota is unusual in that its two main cities are neighbors separated by a river. St. Paul is the state capitol, while Minneapolis is its commercial center. Together they are known as the Twin Cities.

39 See Appendixes 1 and 2, MDH organizational plan and the MDH Smallpox Vaccination Plan organization chart.

Decentralize. The work chart became more complex when the plan drafters decided to decentralize the vaccine program. This was atypical for Minnesota. An outbreak of hepatitis, for example, would be managed at the state level. The decision to decentralize was driven in part by the allocation of funding and in part by the structure of public health in the state. On the funding front, the federal bioterror prevention program (which had created OEP) had brought Minnesota public health $18 million.[40] Of that, $2 million were Health Resources and Services Administration (HRSA) funds earmarked for hospitals for preparedness. The remaining $16 million went to MDH, which disbursed a little over $5 million to local public health authorities.[41] Typically, local health departments provided basic services: environmental health, sanitation, public health nursing, simple vaccinations. Now MDH decided that pre-event smallpox vaccinations would be the local health authorities' first anti-bioterrorism activity. Explains Danila:

> "Vaccines would come to us [at MDH], and we'd deliver it out. We'd be responsible for developing policy, developing materials, developing training. But locally they would be setting up the specifics: size of clinics, where the clinics were, how many clinics and so forth."

Decentralization also made sense given the structure of Minnesota public health. Public health policy was formulated at the state level, but services were delivered at the local level. There were nine public health regions across the state, subdivided further into 51 Community Health Boards charged with local public health service delivery. The smallpox program designers decided to organize smallpox clinics by region. This allowed them to tap existing resources. For example, OEP had already hired a bioterrorism coordinator for each region. Those coordinators, some of them hired only a week before the Bush smallpox vaccine announcement, were quickly co-opted for the new project.

At the same time they were designing the program and its management structure, Ehresmann and Danila had to organize the participants. As early as the week of December 2, MDH sent out general advisories to district and local public health staff, to hospital CEOs, and to regional hospital coordinators. During that week, agency officials held three conference calls with local public health officials and four calls with hospitals to discuss the program and ask for feedback. "We got very specific very quickly," recalls Hull. Typically during those conversations, an OEP official would give an overview, then Danila would provide details about smallpox, the vaccine, and infection control issues.

Dealing with Hospitals. There was a special challenge in dealing with hospitals. MDH had to engage their cooperation at the same time it built relationships with them. Hospitals, most of them privately owned, were under no legal obligation to take part in the vaccine program.

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[40] This constituted Minnesota's share of a $918 million national appropriation for bioterror defense.

[41] The allocation depended on population, so the most sparsely populated county received $15,000, while the most densely populated got $900,000.

Traditionally, MDH dealt with hospitals only infrequently—usually over infectious disease outbreaks. It licensed hospitals, but had no fiscal authority over them. "We had to build a relationship with hospitals out of nothing," says Einweck. OEP had recently created—for the mass smallpox vaccine program—a position of liaison with hospitals. This coordinator now became involved in the pre-event vaccine program.

In the conference calls with hospitals, MDH discussed how to develop criteria for hospital involvement, how to identify the number of staff necessary to care for patients in each hospital, how to decide who would be vaccinated, and who would monitor wound care afterwards. Hospitals were asked to submit the proposed composition of their healthcare teams by December 6. For their part, the hospitals had numerous questions about liability, compensation, funding, and furloughs for employees. "All these were unanswered at that time," remembers Danila.

Dressings. MDH during the first week of December also tackled the question of what kind of bandages to provide for the vaccine site wound to prevent "shedding." Unsurprising to some, the CDC guidelines failed to mention details like this. MDH decided to research available bandages to find the safest product available. In meetings with bandage manufacturers, MDH eventually spoke with representatives from Smith & Nephew, Inc., a British firm. Their product combined in one piece a semi-permeable membrane and gauze. That meant one person could change the dressing by himself, rather than requiring two people. Moreover, the bandage could be left on for 2-3 days, reducing the maceration to the scab that daily changing—recommended by CDC—would have caused. Minnesota was the first state to contact Smith & Nephew and, in placing its order for 50,000 bandages, depleted the firm's worldwide inventory.

Despite such additional distractions, as December 9 approached MDH was on target to complete its plan. Just to complicate matters, the department was also preparing, as part of federal bioterrorism defense efforts, a required plan for steps it would take in the event of an actual smallpox attack. The 175-page smallpox response plan was filed with CDC on Monday, December 2. One week later, on Monday, December 9, MDH submitted its plan for Phase 1 of the smallpox pre-event vaccination program.

Program Announcement

Events continued to move quickly. Within the week, on Friday, December 13, 2002, President Bush announced that the nation would start vaccinating against smallpox. "To protect our citizens in the aftermath of September the 11th, we are evaluating old threats in a new light," said Bush. "Our government has no information that a smallpox attack is imminent. Yet it is prudent to prepare for the possibility that terrorists who kill indiscriminately would use diseases as a weapon."[42] Some 500,000 members of the military would be vaccinated immediately. In

[42] Connolly and Millbank, "US Revives Smallpox Shot."

addition, Bush clarified, states would start as soon as possible to implement individual plans to inoculate an estimated 500,000 healthcare workers nationwide. Those emergency workers would be responsible, in the event of a smallpox outbreak, for tracing and treating smallpox patients, as well as for conducting the first of the mass vaccinations to follow. The program, which was voluntary, would later expand to include 10 million first responders, and the general public could be vaccinated within a year.[43] Bush declared that as commander-in-chief he, but not his family, would be vaccinated.[44]

Deadline Relaxed. At the same time that Bush announced the smallpox vaccination program, federal health officials extended the deadline for completing it. Just before Bush's announcement, the CDC realized that states could not complete their vaccination programs within 30 days of the announcement because, inadvertently, the Homeland Security Act-Section 304 did not include an effective date for the liability protection it conferred. That meant the protection would not come into legal effect until January 24 (60 days after the bill's signing) and even then only if Secretary Thompson made an emergency declaration. For state planning purposes, that meant no vaccinations could begin until January 24, nor could states be certain they were covered for liability until Secretary Thompson made his declaration. Time was still short but not as desperately short as initially thought.

The deadline extension, while it undeniably brought relief, also produced something of a letdown at MDH, which had been working flat out to be ready for the 30-day implementation. Recalls Hull: "We took them at their word. And we were prepared to do it. And so we felt a little bit foolish for believing that." OEP Director Einweck remembers the abrupt interruption to momentum. He says:

> "We thought we were going to be implementing a smallpox vaccination program in December … We literally stopped everything. People canceled vacations, we were working really hard at the local and the state level. Then all of a sudden, it was like—well, sorry … I felt like I was a little steel ball on a pinball machine."

On the plus side, more time allowed MDH to deliberate once again over whether or not to join the vaccination program.

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[43] Bush mistakenly said that members of the public who wanted it could demand a vaccination immediately. In succeeding days, public health officials clarified that vaccination was not recommended for the general public, and that while members of the public might be able to get the vaccine in mid-2003, it would be only as participants in clinical trials of new types of vaccine.

[44] Bush was vaccinated in private on December 21, 2002.

MDH Debates

President Bush's announcement meant that MDH either had to move ahead with its December 9 plan, or declare publicly that it would not take part. Many at MDH had hoped that Bush would provide a stronger rationale for moving forward. "We did expect a stronger statement: that there is an imminent risk, there is an imminent health threat, something like that," recalls Danila. "What we got was less than that… There were still lingering doubts among us whether or not we should participate." Health Commissioner Malcolm, remembers Ehresmann, "was really pulling back, asking 'Do we really want to be doing this?'"

The doubts of public health officials in Minnesota were mirrored on the national level. Former CDC Director Dr. Jeffrey Koplan, for example, said that "I'm not a security expert, but if you are going to ask people to use a vaccine with known and significant side effects, then you've got to make a very good case that the risk of exposure to the disease is real, tangible, quantitative and worth the risk you are going to take with your patients."[45] But others, such as Senator Bill Frist (R-Tennessee), a surgeon who had recently written a book on bioterrorism, supported the plan. "A vaccinated population, even a partially vaccinated population, is a protected population," he told a bioterrorism conference on December 11.[46] CDC Director Julie Gerberding also endorsed the plan: "Although the possibility of an intentional release of smallpox is not quantifiable, the consequences of an outbreak would be great and we must be prepared."[47]

In Minnesota, MDH held staff meetings on Monday, December 16 and again on December 17, to discuss participation. A few staff, notes Danila, expressed their view that "this is against all public health principles that I have" and refused to take part in the vaccination program. "This was a very emotional time," he comments. But eventually, says Danila, most of the resisters realized "that the program was going to occur anyway… We decided that, if we were going to have the program and if anyone was going to get vaccinated, then we were going to make it the safest program possible." Remembers Ehresmann: "It got to the point where it just felt like there was a national push and we were riding the wave… It was a patriotic thing, too... Public health was unable to 'just say no' in this situation even though the debate raged." There was also an issue of responsibility, she adds.

> "You are responsible for the health of the citizens in Minnesota, and if you had the opportunity to plan and you did not take it, or by having people vaccinated that's going to make you more prepared and you didn't do it—then you're screwed. It was truly a lose-lose situation."

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45 Connolly and Millbank, "US Revives Smallpox Shot."

46 Connolly, "President reviving program to provide smallpox vaccine."

47 CDC Press Release, "CDC initial review of state smallpox vaccination plans complete," December 12, 2002. See: www.cdc.gov/od/oc/media/pressrel/r021212.htm

It was also important, though perhaps more so to the political appointees running the department than to the doctors in the Infectious Diseases division, that Governor Jesse Ventura very much supported the smallpox vaccine program. By Christmas, MDH was fully committed to implementing its plan to inoculate some 10,000 health care workers.

Amending the CDC Template

Mid-to-late December continued busy for Ehresmann and her team. They recruited MDH staff for the wide variety of tasks at hand: to liaise with local public health coordinators; to manage administrative functions such as finance, technology, legal issues and tribal health; and to take charge of "adverse event" (negative reaction to the vaccine) surveillance. Ehresmann also filled positions for data management, vaccine handling, communications, clinic operations, a web site, and to link with the health alert network. Finally, she appointed individuals to liaise with field epidemiologists, with hospitals and with federal agencies. A core team led by the Commissioner of Health met regularly to review progress, although there was a change of personnel on January 5, 2003, when Commissioner Malcolm stepped down with an outgoing administration and Assistant Commissioner Leitheiser became Acting Commissioner.

Meanwhile, MDH took advantage as much as possible of materials and training CDC provided. On December 5 and 6, health workers had watched a CDC smallpox vaccine education program. The week of December 16, a doctor and four nurses prepared to fly to Atlanta to learn how to give smallpox shots.[48] CDC scheduled another nationwide satellite broadcast on smallpox vaccine risks for Friday, December 20, which MDH staff attended.

But there was much MDH felt it had to invent for itself. For example, in late December it occurred to MDH officials that someone would have to handle negative reactions to the vaccine. The department hastily created a network of physicians who would be on call around the clock. CDC suggested a similar system to all states only later, and offered training for clinicians in early February. Minnesota by then had long since organized a group of some 75 doctors who would take calls from vaccinated persons worried about a rash or other symptom. In addition to general practitioners, the network included opthamologists, dermatologists, and infectious disease specialists.

Minnesota became the first state to point out that CDC could not require vaccination of those who checked smallpox vaccine dressings. ACIP, in its October recommendations, had insisted that dressing checkers be vaccinated. But hospitals, MDH informed ACIP members, could not afford this measure. Were it insisted on, they would drop out of the program. As a result, ACIP in its January recommendations amended its earlier stance and suggested that checkers be

[48] Maura Lerner, "State's plan for smallpox takes shape," *Minneapolis Star Tribune*, December 13, 2002, p.1A.

vaccinated only if feasible.[49] MDH also was one of the first states to raise the question of how to care for *vaccinia* patients—those infected by the vaccine or secondary infections. The Minnesota officials were particularly concerned about infection control. Lacking guidance from CDC, MDH developed its own protocols for the care of *vaccinia* patients.

While it was satisfying in some ways to be out ahead of the CDC, State Epidemiologist Hull would have preferred clear, well-conceived directives. "On a number of occasions," he muses, "my feeling was that the advice we were given was from a couple of people who didn't have a clue about how state health departments work, sitting in a bar and writing out the solutions on a napkin."

> "They've not been thought through. They don't reflect an understanding of our relationship with the local health departments, and how local health departments work."

The CDC hadn't considered practical details, says Hull, such as "who's going to cover the patients [while hospital workers are vaccinated]? Who's going to pay for the transportation? Who's going to pay the salary time?" In a state the size of Minnesota, it could take a day to drive to a designated regional clinic site and back.

Target Date. Despite these difficulties, by late December Minnesota felt sufficiently prepared to tentatively schedule its vaccination clinics to begin on January 27. In early January, however, MDH learned it need not have rushed. By then, the department was already nervous about the January 27 date. In a memo dated January 10, 2003, Acting Health Commissioner Leitheiser asked the Association of State and Territorial Health Officials (ASTHO), which monitors federal public health policy, whether it could confirm that Secretary Thompson would issue his declaration on January 24, thereby activating the Section 304 liability protection. Also, there were rumors that vaccine would not ship until February 3. With clinics scheduled for January 27, Minnesota needed to know what the schedule was. "Canceling clinics at the last minute will waste time and money, discourage participation, and make it very difficult to go through another round of planning," wrote Leitheiser.[50]

Before that letter could arrive at ASTHO, however, a neglected fact came to light. Many states had continued to believe that, although the earliest smallpox clinic start date had been pushed back to January 24, they were still expected to complete the vaccination program within 30 days. In Minnesota, says Einweck, "we were under the impression that we had 30 days to do all of our vaccinations because the liability protections would only be in place for 30 days." However, on January 10, Minnesota and other states learned in a conference call that the vaccine program did

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[49] Oddly, ACIP never required vaccinations of those caring for *vaccinia* patients.

[50] Source: Memo from Leitheiser to George E. Hardy, Jr., January 10, 2003, 9:34 a.m., re *Smallpox Pre-event Issues*.

not have to wrap up within 30 days of starting after all; in fact, the states had a year's liability coverage.[51]

CDC Director Gerberding explained in an interview the following week that the 30-day deadline was "another complete misunderstanding. The bottom line … is that there is no end date for this program."[52] She also pointed out that the smallpox vaccine program had no set goal for numbers vaccinated: "We need to get away from this notion of a number." Federal officials, she added, had deliberately overestimated to make sure sufficient vaccine would be available: "We knew full well that we did not need to vaccinate that many people." She noted that safety, not speed, was the CDC's priority. "Because the smallpox threat is not imminent, we can put safety as our highest priority," Gerberding said.

Meanwhile, the January 10 CDC conference call also confirmed Leitheiser's worry about getting vaccine on time. MDH learned that CDC had concerns over liability if it started shipping before January 24. It told the states that it *could* start shipping as early as the week of January 13, but would not confirm that it *would* ship then. The reaction at MDH, recalls Einweck, was resignation: "In Minnesota, we were really trying to be a good soldiers, get all our plans in place, only to find out later oh, well—we really didn't mean that… So we said let's just get this over with." MDH re-scheduled the first clinic for February 12.

But before it would vaccinate even one volunteer, MDH—like other public health departments nationwide—wanted to settle to its own satisfaction the liability and compensation questions that had beset the pre-event vaccine program from its conception.

Liability and Compensation

By January, there was a groundswell of anxiety from states about the unresolved liability and compensation issues. On January 9, Secretary Thompson sent a letter to states assuring them that liability issues had been taken care of and they should not worry. But this did not reassure MDH. Acting Commissioner Leitheiser's January 10 letter to ASTHO also posed specific questions about liability and compensation. Minnesota wanted to know about 1) liability coverage under the Homeland Security Act for clinicians who were not vaccinators but who screened, managed adverse events or cared for secondary transmission cases; 2) coverage for hospitals which did not host clinics but permit vaccinated employees to work; 3) compensation for vaccinated persons who did not have workers compensation or were otherwise incompletely covered for missed work or medical treatment; and 4) arrangements for compensating and providing medical care for those with secondary infections.

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[51] Secretary Thompson clarified the liability schedule two weeks after the conference call.

[52] Vicki Kemper, "States lag at start of smallpox program," *Los Angeles Times*, January 17, 2003, p.1. The other quotes in this paragraph are also from this article.

MDH also contributed to a document compiled by a number of states under the auspices of ASTHO, along with the National Association of City and County Health Officers (NACCHO). The ASTHO/NACCHO document listed state concerns over liability and compensation. It noted, for example, that because the smallpox response teams benefited society, "any attendant costs should be born by society-at-large and not by the local community or individual."[53] It called for a "uniform national solution" to state concerns over institutional and personal liability for ill-effects of the smallpox vaccine and a "comprehensive national approach" to injury compensation.

The document identified a number of shortcomings in the Homeland Security Act-Section 304, such as the fact that individuals must prove negligence—a heavy burden—in order to sue the federal government for injury from the vaccine. It pointed out that workers' compensation schemes differed from state to state and were therefore not equal; that workers' compensation in most cases did not cover a waiting period nor provide full salary; that compensation for minor side effects was not provided; that workers' compensation payouts would result in higher premiums; that no reimbursement was provided for furloughs. The document wanted no-fault compensation for any person injured by the vaccine. It also asked that the definition of "covered entities" be broadened to include public health departments, hospitals and other organizations which participated in any way in the vaccine program.

The Bush Administration did respond on January 14 with a ruling that those who administered vaccine or those who received a vaccination would not be held liable if someone else became ill.[54] The Administration refused, however, to create a compensation fund for those who suffered complications from the vaccine. "We are looking at ways to work with all of the involved parties to address issues related to compensation," said CDC Director Gerberding. But, she added, "we are certainly not going to delay this program because of concerns about compensation."[55]

In the midst of this debate, two of the nation's largest unions on January 16 asked President Bush to postpone smallpox vaccinations until the Administration could pay for medical screening of volunteers and compensation for anyone injured. The Service Employees International Union (SEIU), with 750,000 members in the healthcare sector, and the American Federation of State, County and Municipal Employees (AFSCME), with 350,000 healthcare and emergency workers, advised their members not to take the vaccine.[56] The American Nurses Association also sought delay. On January 17, the Institute of Medicine (IOM), an advisory group to the federal government, urged the CDC to proceed cautiously. It said the government should

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53 Source: Draft, *Smallpox Pre-event Vaccination: Liability and Compensation Concerns*, ASTHO/NACCHO Smallpox Liability and Compensation Working Group.

54 Ceci Connolly, "Caregivers protected against smallpox lawsuits," *Washington Post*, January 15, 2003, p.A14.

55 CDC Telebriefing Transcript, CDC Smallpox Vaccination Update, January 17, 2003. See: www/cdc.gov/od/oc/media/transcripts/t030117.htm.

56 Ceci Connolly, "Unions call for changes in smallpox vaccine program," *Washington Post*, January 17, 2003, p.A13.

answer questions about liability and compensation, and should clarify the risks. The IOM also suggested a pause between Phases 1 and 2 to allow time to evaluate lessons learned.

These accumulating doubts and unresolved issues began to have an effect. By mid-January, some half-dozen prestigious hospitals around the country, including Grady Memorial in Atlanta and Virginia Commonwealth University Health System in Richmond, had decided not to participate in the vaccine program. Minnesota hospitals were starting to make the same choice.

Participation Rates

MDH had long since realized it would not attract the 10,000 volunteers envisioned in the December 9 plan. In late December, when it set January 27 as a target starting date for clinics, MDH planned to ask CDC for 4,500 doses of vaccine. But as Minnesota drew closer to the revised clinic start date of February 12, even that number began to look optimistic.

MDH in mid-December had identified 66 of the state's 142 hospitals as qualified to treat smallpox patients. That number soon emerged as too high. It included some hospitals which did have the required negative pressure isolation room, but which were otherwise small and/or rural, and unequipped to deal with an influx of smallpox patients. Seven of these hospitals informed the state by early January that they would not participate; a couple of others dropped out for other reasons. As of early January, however, 52 had agreed to participate.[57]

But as January progressed, a number of qualifying hospitals declared their intention not to vaccinate any staff. The number of non-participating hospitals was small, but their publicity impact was high. On January 9, North Memorial Medical made headlines with its decision to delay any action. North Memorial was the first hospital in the St.Paul/Minneapolis metropolitan area to pull out. The hospital's vice president expressed concern over the risk of the vaccine to staff members and to patients. On January 26, another three hospitals from one network opted out: St. Joseph's in St. Paul, St. John's in Maplewood and Woodwinds in Woodbury. They cited health threat concerns. On January 30, United Hospital in St. Paul said it had not decided whether to participate. If United dropped out, only two hospitals—albeit large ones—in St. Paul would be prepared for smallpox patients. By early February, 42 Minnesota hospitals still agreed to participate; 24 had said no.[58]

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[57] Maura Lerner and Jill Burcum, "Metro hospital is opting out of smallpox plan," *Minneapolis Star Tribune*, January 9, 2003, p.1A.

[58] Maura Lerner, "Homeland Security: Osterholm defends national smallpox program," *Minneapolis Star Tribune*, February 10, 2003, p.1A. By way of comparison, Johns Hopkins Hospital in Maryland announced January 30 that it would go slow, vaccinating five or six workers a week on a voluntary basis for 6-9 months, and keeping them away from patients as they reacted to the vaccine. The hospital would provide its employees medical treatment and compensation for time off work, if needed. Source: Erika Niedowski, "Hospitals outline smallpox vaccination plan," *Baltimore Sun,* January 31, 2003, p.2B.

At the same time, the sign-up for the vaccine even at participating hospitals was considerably lower than expected. At St. Cloud Hospital, only 22 of an expected 210 health workers had volunteered by January 18.[59] Fairview Health Services, operator of seven hospitals, also had fewer volunteers than projected. Some hospitals, however, reported volunteers in line with expectations. Abbot Northwestern in Minneapolis and Hennepin County Medical Center in Minneapolis were close to meeting their goals. Of those medical workers who chose not to participate, many cited children at home—who might become infected—as the reason for declining. Some doctors dropped out because, as self-employed persons, they didn't carry workers compensation insurance.

MDH had few tools at hand to increase participation rates. Persuasion was its strongest suit. After that, it could only try to make the best of the situation at hand. State health officials repeatedly reassured the public that lower numbers of vaccinees would not leave the state unprepared. "What we're trying to do is make sure that the entire state is prepared," Hull said, by putting "a team in every appropriate hospital. But one of the key points that has to be made here is that a vaccination can occur after exposure for up to four days. In most scenarios, we would be able to protect the people even after exposure."[60] Buddy Ferguson, communications staff member at MDH, said that "I don't think we are concerned at this point that we won't be able to vaccinate enough people."[61]

> "The idea is to have minimal numbers of people vaccinated in advance of an actual event so they could respond to it. But again, you can vaccinate people even after they've been exposed to smallpox. That's the backup."

Hull also felt that participation rates were driven lower by overreaction to the perceived risk. People did not properly understand risk ratios. A risk ratio of 1 in 50,000, for example, "is the risk of dying on the way to work if you drive to work five days a week, 50 weeks a year for 200 years," says Hull. "So a 1 in 50,000 risk is something that we take virtually every day without thinking about it." The smallpox vaccine, given after careful screening, carried something closer to a miniscule 1 in 500,000 risk.

The federal government, for one, was convinced the risk was justified. On Friday, January 17, the CDC finally announced it would begin shipping vaccine on Tuesday, January 21. Eleven states, said CDC Director Gerberding, had requested shipment. "We intend to make this program happen on time," she told a press conference. "We live in a dangerous world these days where a terrorist attack with smallpox is possible… We have to be prepared so that we can protect the

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59 Josephine Marcotty and Maura Lerner, "Smallpox signup is less than expected," *Minneapolis Star Tribune*, January 18, 2003, p.1A.

60 Lerner and Burcum, "Metro hospital is opting out of smallpox plan."

61 Marcotty and Lerner, "Smallpox signup is less than expected."

American people."[62] Gerberding also spoke to some of the doubts expressed about the purpose of the smallpox vaccine. "Sometimes," she said, "it is difficult for people who are thinking of this from a totally public health perspective to recognize that this decision is not just a public health decision. This is an issue of homeland security and an issue of national defense."

National Program Launches. On Friday, January 24, Secretary Thompson made his long-promised emergency declaration, which allowed Section 304 of the Homeland Security Act to take effect. To mark the official launch of the smallpox program, four doctors in Connecticut that day became the first in the nation to be vaccinated. Four was far fewer, however, than the 20 participants Connecticut had advertised. Most of the no-shows, according to press accounts, were worried about compensation.

Get it Over With

With the green light given, MDH finalized its preparations for clinics to start February 12. The same day the national program launched, MDH secured a pledge from the Minnesota Department of Labor and Industry that any state worker made ill by the vaccine would be covered by workers' compensation. That ruling would not cover non-state employees. But the state ruling established a precedent and would, MDH officials hoped, set an example for the roughly 400 private sector workers' compensation programs across the state.

MDH also finalized the packet of materials sent to each prospective vaccinee. The CDC was still revising the documents it wanted included. But MDH decided it could wait no longer. The department wanted vaccinees to receive their packets at least a week in advance and thousands of copies had to be made. "At a certain drop-dead date," remembers Danila, "we said it doesn't matter if the CDC is revising it at this point. We're going to make our copies now." MDH also added its own original documents to the packet, such as a warning on latex allergies, one on dressings, and some state-specific privacy forms.

During the last weeks of January, MDH held vaccination training by satellite for over 800 individuals, mostly nurses. On January 29, MDH ordered 4,500 doses of vaccine, less than half the amount proposed in the December 9 plan. It arrived on February 4. At this point, the department expected to vaccinate 2,700 volunteers—1,700 hospital personnel and 1,000 public health workers—over a period of "several weeks."[63]

The Minnesota pre-event smallpox vaccine program opened on February 12 with a clinic at the state emergency operations center in the Department of Public Safety building in St. Paul. Because of security concerns, MDH had kept the location secret until the last moment. Television

[62] CDC Telebriefing Transcript.

[63] MDH news release, February 10, 2003. See: www.health.state.mn.us/news/pressrel/spox021003.htm

cameras were invited to witness the first vaccination, that of State Epidemiologist Hull. Hull, who had been vaccinated three times already, said afterwards "I couldn't even feel it."[64] Only five volunteers were vaccinated in front of the cameras; others were inoculated in another, confidential location. Dr. Gregory Poland, a smallpox expert at the Mayo Clinic in Rochester, Minnesota, who had long been immunized himself, administered the televised vaccinations.

For the next five weeks, clinics were held regularly in unpublicized sites around the state. Eventually, local public health departments hosted nine regional clinics, while another 30 or so satellite clinics were held at hospitals. The vaccination procedure was time-consuming, taking up to an hour per patient, because the protocols for administering the smallpox vaccine were closer to those required in drug trials than to standard immunization clinics. Much time went to screening each volunteer to discover if he/she had any reason not to take the vaccine. Counter-indications included pregnancy or a desire to become pregnant soon, eczema, a recent case of skin disease of any kind, allergies to medications, or an immune-compromised system due to treatment for cancer or other illnesses. Any borderline case was referred to a second screener. The potential vaccinee was then shown a CDC-produced film warning of the risks of the vaccine. Finally, each vaccinee had to sign a consent form acknowledging agreement to be vaccinated.

Eventually the vaccine was administered. The vaccinator unwrapped the two-pronged needle, dipped it in the vaccine vial to trap drops between the prongs, then pricked the skin on the upper arm 15 times. The spot was covered with the two-layer bandage MDH had special-ordered. The site had to be kept covered for roughly two weeks to prevent shedding. Next, a nurse showed the vaccinee how to care for the wound site properly, including bandage changes. Finally, a public health worker conducted an exit interview. Over the next 19 days, each vaccinee also reported for regular checks to a healthcare worker who ascertained that the vaccine had "taken."

As the program unfolded, problems inevitably surfaced. Some had been foreseen, others took officials by surprise.

Kinks and Costs

The organizational structure arrived at so hastily in early December proved one obstacle to smooth operations, at least in the eyes of some. A few state officials felt they gave up too much policy authority, while locals complained of contradictory instructions from too many masters. Many clinics, for example, decided to inoculate laboratory technicians because the number of volunteer healthcare workers was small. The original MDH guidelines had allowed for this local discretion, and many MDH officials, says Ehresmann, continued to believe that was a good strategy. But Deputy State Epidemiologist Danila, for one, came to feel that such autonomy was an

[64] Maura Lerner, "US Prepares on Multiple Fronts: State smallpox effort starts with both secrecy, publicity," *Minneapolis Star Tribune*, February 13, 2003, p.1A.

error. "I'd say that's wrong," comments Danila, noting that ACIP specifically prohibited vaccinating lab technicians.

> "Locally they'd say, 'Well, you gave us flexibility to make local decisions.' I would say that was a mistake on our part. We should not have had flexible policy decisions. There should have been a clear line of authority."

Danila would have preferred to see a master list of all potential vaccinees and their roles, with a central authority deciding yes or no in each case. "That," he notes wryly, "was not done." From the other end of the spectrum, Jane Norbin, director of the Health Policy and Planning section of the Saint Paul—Ramsey County Department of Health, feels that local health officials' autonomy was constrained: "You have a lot of autonomy to do it your way as long as you follow the way you are told to do it."[65] She complains that state responses to local inquiries were not consistent: "You'd get an answer from one person, and another one would contradict it. That was very difficult." Danila agrees that the chain-of-command was poorly conceived. A single hospital with a single question had to send its query through multiple layers of authority. "By the time it gets to us, it's like telephone tag. What gets said and what gets done is not clear," he says.

Diverting Resources. Another problem, anticipated but nonetheless real, was the diversion of resources—both people and money—from other health needs. Public health nurses who normally did clinic immunizations or visited at-risk mothers had been diverted to smallpox. Nurses who worked for the federal Women, Infants and Children (WIC) program, which provides nutrition and healthcare advice to low-income families, were now doing smallpox training. Elderly people experienced delays in screenings for admission to nursing homes. Minnesota was not alone—states across the country reported trimming services such as prenatal care, AIDS prevention, water testing and tracking tuberculosis. Public health nurses had been diverted to smallpox from childhood immunization, new mother visits and diabetes screening.[66]

OEP Director Einweck told the House Health and Human Services Policy Committee on January 29 that "we're very concerned about being able to meet all our other grant requirements at the state and county level."[67] MDH, for example, had hired experts to help plan for radiological or chemical terrorism but these people had been diverted to smallpox. Another program to train all health workers in bioterrorism emergency procedures had been put on hold.

As for expenses, it was hard to estimate how much the smallpox vaccine program cost the state because most of the expense came in the form of diverted personnel. State employees such as Danila had devoted weeks to smallpox. It was impossible to put a value on the other tasks they

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65 Author's interview with Jane Norbin, St. Paul, MN, on March 27, 2003. All further quotes from Norbin, unless otherwise attributed, are from this interview.

66 Ceci Connolly, "Smallpox campaign taxing health resources," *Washington Po*st, March 10, 2003, p.A4.

67 Jean Hopfensperger, "Anti-smallpox effort is strapping counties," *Minneapolis Star Tribune*, January 30, 2003, p.1B.

had not accomplished. But there were hard costs as well. The 50,000 specialty bandages MDH ordered, for example, cost 74 cents apiece.

The federal government had suggested that states simply redirect to the smallpox program the bioterrorism monies they had received in the spring. But after MDH officials did just that, says Einweck, the accountants at CDC asked for exhaustive accounts of where the money had gone and why. Not that the $18 million Minnesota had received was sufficient. Mary Wellick, director of the Olmsted County Public Health Department, complained to the House Health and Human Services Policy Committee that "no local health department has adequate funding for [smallpox] clinics at this point."[68]

> "Our services are right against the wire. We had planning money, but no implementation money. And even the planning money is running out."

Einweck testified that while not all 87 Minnesota counties were experiencing budget problems, those running the vaccination clinics were hard hit. Unanticipated expenses included the price of security details. These were arranged, Einweck explains, because CDC had required them. To MDH dismay, CDC in March said that that was incorrect—security coverage had always been a local decision "based on your own internal risk assessment." But by then the money was spent.

Hospitals, meanwhile, incurred their own costs—with no prospect of reimbursement from the state. They had to pay for time to educate vaccinators and vaccinees, for time both groups spent away from their customary work, and for time staff spent checking the bandages of those vaccinated. There was also the cost of setting up the clinics and taking them down. A few hospitals reported bills in excess of $100,000.

Other states also complained about costs and diverted resources. In a NACCHO survey of 539 health departments released in February, some 79 percent said the smallpox vaccine campaign was using up staff time and money meant for other anti-bioterrorism programs, such as upgrading laboratories, building secure communications, training staff, and planning for chemical or radiological attack. Even at CDC, almost all of the 350 immunization division staff had been reassigned to smallpox.[69] As for money, in December ASTHO Executive Director Hardy had called the smallpox vaccination campaign "the ultimate unfunded federal mandate… We can't afford to do this at the expense of all other preparedness."[70] Patrick Libbey, executive director of NACCHO, added that "states and localities already are diverting significant resources to smallpox vaccination and there is no end in sight."

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[68] Ibid.

[69] Ceci Connolly, "Smallpox campaign taxing health resources," *Washington Post*, March 10, 2003, p.A4.

[70] Ceci Connolly, "Smallpox plan may force other health cuts," *Washington Post*, December 24, 2002, p.A1.

> "We urge that the program be kept at minimal levels and grow only as rapidly as threat assessments demand, so as not to disrupt other basic community health protections or cause unnecessary harm."

So it was with considerable relief that, by mid-March, MDH officials concluded that all healthcare workers who would volunteer for the smallpox vaccine had done so. Minnesota had vaccinated some 1,400 people—ranking the state fourth in the nation for absolute numbers vaccinated. Turnout among public health employees, as at the hospitals, had been lower than anticipated. "A lot of interest," Ramsey County Health official Norbin characterizes the situation, "but very few at the end actually got vaccinated." Out of the 330 people in her department, for example, fewer than 10 were vaccinated. Phase 1, MDH officials hoped, was officially drawing to a close. But the federal government had other ideas.

Phase 2 Already?

It had been clear for some time that the federal government was not happy with the slow pace of inoculation. By early March, with the compensation issue holding so many states and hospitals back, only 12,404 healthcare workers had been immunized out of the 500,000 Thompson had hoped for by March 1. Hundreds of hospitals across the country had refused to participate.

So the Bush Administration on March 5 finally agreed to a limited compensation plan for those injured by the vaccine. Drafted by HHS and the White House, the proposal offered $262,100 in benefits to those who died or suffered a permanent disability from the smallpox vaccine. Moreover, HHS would pay two-thirds of lost wages, up to $50,000 a year, for those temporarily or partially disabled up to a cap of $262,100. Those payments would begin only after missing five days of work. The same benefits would go to those with secondary infections. The plan would now have to go to Congress for approval. In a caveat, however, the plan covered only those vaccinated in the first 120 days after the bill's passage—not those who participated later.[71]

One day later, Secretary Thompson took a second step to jumpstart the smallpox program. There had never been a firm timetable for starting Phase 2, just as CDC had never provided any definition of what constituted success in Phase 1—number of teams successfully vaccinated, caregivers per hospital or other measures. But on March 6, HHS gave states permission to move into Phase 2 of the vaccine program. The decision seemed to be driven by the low numbers of healthcare workers vaccinated so far. The government needs, said Thompson, "to make sure we have enough people prepared" for a smallpox attack.[72] "There is no question," he said, "we wish

[71] Rick Weiss, "US Surgeon General to get smallpox shot," *Washington Post*, March 11, 2003, p.A21.

[72] Ceci Connolly, "Smallpox vaccination campaign bolstered," *Washington Post*, March 7, 2003, p.A31.

there were more people willing to be vaccinated."[73] On March 7, Thompson arranged a conference call with the public health commissioners of all the states to discuss moving into Phase 2.

Minnesota was one of several states dismayed at the prospect of moving into Phase 2 with little guidance or advance planning. There was no question of hospitals doing any more vaccinations; public health staff would have to assume the full burden of running clinics. MDH wanted to assess what had been accomplished in Phase 1 before moving on to Phase 2.

Ramsey County Wants In

Yet starting in early March, pressure began to build to do just that. It began with the sheriff of Ramsey County, home to the state capital St. Paul. Back in February, Sheriff Bob Fletcher had called the Ramsey County health department to ask for smallpox vaccinations for two top officials from his office. Those two were vaccinated on February 21 under the provisions of Phase 1 to inoculate a few public safety officials. The Ramsey County public health clinic also vaccinated a third official from the sheriff's office and a police officer from St. Paul on March 3 as part of Phase 1. But then the sheriff spoke with the mayor of St. Paul, who upped the ante—he asked for vaccinations for all city police and firefighters.

Sheriff Fletcher, says County Director of Health Policy and Planning Norbin, "had done his own research on smallpox and smallpox vaccine… and was convinced that we needed to have a vaccinated first responder corps." The sheriff's department alone numbered 250 people. Even if only half of them qualified for the vaccine, that would be a large group to vaccinate. Norbin told the sheriff that MDH would let him know as soon as Phase 2 started, but he objected. "His response," recalls Norbin, "was 'Who do I have to call to get this going? I'm calling our state senators. I'll call the governor. This is unconscionable that public health would hold this up. They did themselves, and they won't do first responders?'"

When MDH heard about the Ramsey County request, not to mention Secretary Thompson's March 6 announcement, many reacted strongly against it. Deputy State Epidemiologist Danila was unambiguous about where he stood:

> "Some of us are clearly drawing a line in the sand right now and we will not do that [Phase 2]. We certainly will not do that in the same way we've done Phase 1. We cannot maintain this pace that we've been on."

On March 10, Danila sent an email to many of the state's top health officials, including Leitheiser—now back to being assistant commissioner for health protection. "Several of us," Danila began, "feel very strongly that we cannot continue at the current Phase 1 level of detail,

[73] Several hundred federal healthcare workers at CDC, the Public Health Service Commissioned Corps and rescue workers would also be vaccinated.

quality of patient safety, and pace of operations beyond March 31."[74] Hospitals, too, he said, had told MDH they could not go beyond Phase 1. The pressing need now, he argued, was to evaluate: How many vaccinators have been vaccinated and where are they? How many disease investigators? How many patient care providers, at which hospitals? What Phase 1 gaps exist in Minnesota and how will they be addressed? Danila continued:

> "We also feel strongly that we are becoming less prepared, not more prepared, for smallpox by focusing on vaccinating more persons rather than examining and exercising our post-smallpox event plans."

Hull agreed, noting that "promoting vaccination to create the illusion of preparedness doesn't take us any place." In addition, there were costs in terms of time and staffing requirements. "The attitude from Washington has been 'Well, we gave you $16 million, get on with it.' [But] that was for other purposes and it doesn't do anything to compensate the hospitals," says Hull.

At the same time, Assistant Commissioner Leitheiser was reporting via email to Susan Heegaard in the office of newly-elected Republican Governor Tim Pawlenty. Pawlenty was close to the Bush Administration.[75] Heegaard was the governor's designated liaison with the departments of Health, Human Services and Education. On Thursday, March 6, Leitheiser alerted Heegaard to the fact that the Ramsey County public health department was feeling pressure to vaccinate local law enforcement officials. She identified four problems with the request:

- MDH had been approved by CDC to do public health/hospital teams, not general first responders
- There wasn't enough vaccine to do everyone
- The smallpox vaccine program had been expensive and staff intensive; there were neither the personnel nor money to do a wider program. The current need was for evaluation
- The federal government was working on a compensation package but nothing was in place yet

MDH, Leitheiser reported, would be sending out a letter to all local public health departments asking that all smallpox vaccine be returned. That memo went out the next day, March 7.

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74 Email from Richard Danila to Aggie Leitheiser et al, March 10, 2003, 1:57 p.m., "Phase 2 discussion."

75 Vice President Dick Cheney had asked Governor Pawlenty not to run for the US Senate in the fall 2002 elections so that Norm Coleman could run.

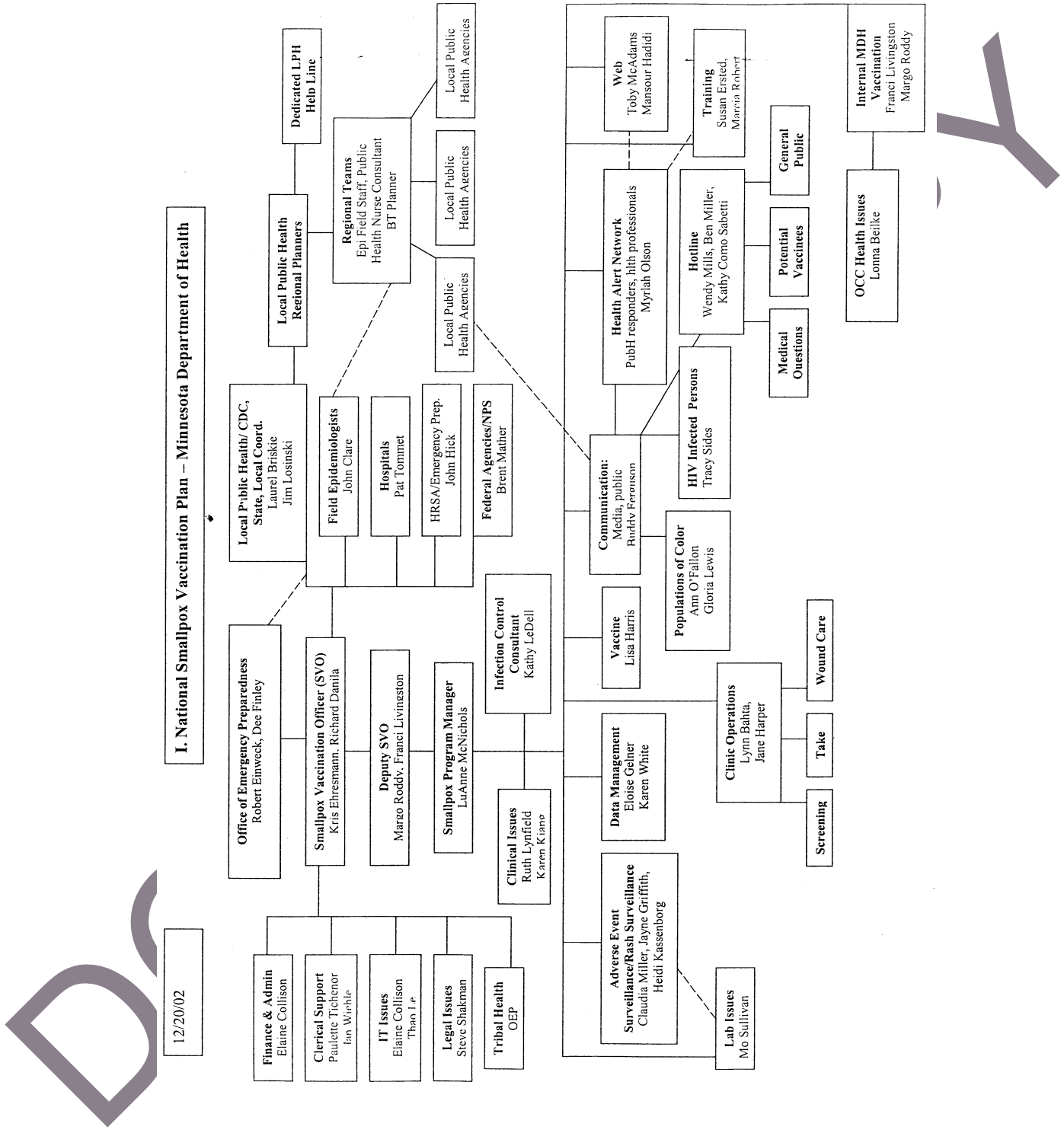
By Monday, March 10, however, Heegaard was pushing back in support of the sheriff's request. The governor's chief of staff Charlie Weaver—who as former public safety commissioner had close ties to law enforcement and fire officials—had said MDH should go ahead and vaccinate local law enforcement officials, starting with Minneapolis and St. Paul. According to Heegard, the newly-appointed commissioner of health, Dianne Mandernach, was in the room for the discussion. "Have you come up with a plan in light of the broad discretion given by the feds?" she asked, referring to Secretary Thompson's March 6 announcement that states could move to Phase 2 at will.

Leitheiser responded early on Thursday, March 13, trying once again to explain the MDH objections to moving to Phase 2 quickly. The department wanted, she said, to offer "Phase 2 in an organized way." She mentioned a number of outstanding issues: medical coverage, training and screening, whether MDH should provide bandages, review of the vaccine "take." She reiterated that hospitals and local public health officials found the costs of expanding vaccinations to first responders "large and that the money isn't there." She reported that, nonetheless, each region had been asked to come up with a Phase 2 plan within a week. MDH would be meeting with local health planners shortly to coordinate activities.

But Leitheiser realized she could hold off for only a limited time. Later on Thursday, Leitheiser called a meeting that included Hull, Ehresmann, Einweck, Danila, and other MDH staff involved with the smallpox program. By the end of the meeting, she told them, they had to decide what to tell the Ramsey County public health department.

Exhibit 1

Exhibit 2


I. National Smallpox Vaccination Plan – Minnesota Department of Health
12/20/02
Office of Emergency Preparedness
Robert Einweck, Dee Finley
Local Public Health/ CDC, State, Local Coord.
Laurel Briskie
Jim Losinski
Local Public Health Regional Planners
Dedicated LPH Help Line
Regional Teams
Epi Field Staff, Public Health Nurse Consultant
BT Planner
Local Public Health Agencies
Local Public Health Agencies
Local Public Health Agencies
Field Epidemiologists
John Clare
Hospitals
Pat Tommet
HRSA/Emergency Prep.
John Hick
Federal Agencies/NPS
Brent Mather
Smallpox Vaccination Officer (SVO)
Kris Ehresmann, Richard Danila
Deputy SVO
Margo Roddy, Franci Livingston
Smallpox Program Manager
LuAnne McNichols
Infection Control Consultant
Kathy LeDell
Clinical Issues
Ruth Lynfield
Karen Kiang
Finance & Admin
Elaine Collison
Clerical Support
Paulette Tichenor
Ian Wehle
IT Issues
Elaine Collison
Legal Issues
Steve Shakman
Tribal Health
OEP
Communication:
Media, public
Vaccine
Lisa Harris
Populations of Color
Ann O'Fallon
Gloria Lewis
Health Alert Network
PubH responders, hlth professionals
Myriah Olson
HIV Infected Persons
Tracy Sides
Web
Toby McAdams
Mansour Hadidi
Hotline
Wendy Mills, Ben Miller, Kathy Como Sabetti
Training
Susan Ersted,
Medical Questions
Potential Vaccinees
General Public
OCC Health Issues
Lonna Beilke
Internal MDH Vaccination
Franci Livingston
Margo Roddy
Data Management
Eloise Gelner
Karen White
Clinic Operations
Lynn Bahta,
Jane Harper
Wound Care
Take
Screening
Adverse Event Surveillance/Rash Surveillance
Claudia Miller, Jayne Griffith, Heidi Kassenborg
Lab Issues
Mo Sullivan