

# TERROR AND TRIAGE: PRIORITIZING ACCESS TO MASS SMALLPOX VACCINATION

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## ABSTRACT

In response to the threat of a smallpox attack on the United States, the Centers for Disease Control and Prevention ("CDC") recommended the establishment of smallpox clinics designed to distribute a vaccine to the entire U.S. population in a ten day period. However, a number of potential obstacles raise questions about the feasibility of this plan. What is needed is a plan that applies principles of triage to smallpox vaccine distribution following a bioterrorism attack. Only in this way can those most vulnerable—the previously unvaccinated—be protected from a significantly increased risk due to delays that might arise in executing the CDC plan.

## INTRODUCTION

In the wake of the bioterror attacks of October 2001, the visibility of smallpox as a potential biological weapon has led to government actions designed to prepare for potential attacks using this agent. In December 2001, the Department of Health and Human Services allocated \$428 million for the development of 155 million smallpox vaccine doses, and studies are being conducted concerning the viability of diluting our existing stockpiles of the smallpox vaccine so that greater numbers of people can be vaccinated in the event of an outbreak.<sup>1</sup> These efforts are intended to increase U.S. smallpox vaccination stockpiles to 286 million by the end of 2002 (enough to cover every U.S. citizen). Distribution of this stockpile, however, remains controversial.

The Centers for Disease Control and Prevention ("CDC"), in their initial interim smallpox response plan and guidelines, recommended a

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1. Marilyn Chase, *Study Suggests Smallpox-Vaccine Supplies Could Be Stretched Safely With Dilution*, WALL STREET JOURNAL, February 6, 2002, at B4.

ring vaccination and monitoring approach coupled with identification of priority "high risk" groups as the preferred tactic to address a smallpox outbreak. Under a "ring vaccination" or "search and containment" strategy, known and suspected cases are isolated from society, and those who have come in contact with such cases are traced, vaccinated and kept under close surveillance. Through this strategy, a "ring" of vaccinated individuals is created to surround the infected, thereby impeding further spread of the disease.<sup>2</sup> However, doubts about the effectiveness of this plan, along with public calls for access to vaccination, have forced the CDC to reevaluate its reliance on the ring vaccination.

Bush administration plans have, at times, called for mass voluntary vaccination of the general public prior to any bioterror event, although such mass vaccination would likely not be carried out until 2004 at the earliest, and more recent administration announcements indicate the administration is leaning toward a more limited availability of the vaccine.<sup>3</sup> We have argued elsewhere that mass vaccination of the general public, pre-event, is unwise. One of the primary reasons for this lies in the low probability that terrorists have access to, and the ability to effectively deliver, this particular biological weapon. Nonetheless, the threat is real. While the low probability just described makes it unwise to expose the public to the risks of smallpox vaccination (mass vaccination itself would likely result in 350-500 deaths, and other serious side-effects, without any overt terrorist act whatsoever), *planning for post-event vaccination* is wise regardless of pre-event vaccination policy. In this context, recent studies on the need to target vaccination for maximum effectiveness should be incorporated into smallpox response plans.<sup>4</sup>

In September 2002, the initial CDC response plan was supplemented with guidelines for conducting a mass vaccination of the entire U.S. population in a ten day period. These new guidelines are to be applauded for reasons we discuss below. However, serious deficiencies remain. Foremost among these is the lack of clear triage plans that prioritize access to a mass vaccination in the event of a terror-related outbreak. Any terror-related outbreak of smallpox will almost surely result in public panic and demand for vaccination that will strain the public health infrastructure. There is a need, then, to devise criteria for the orderly administration of the vaccine even under

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2. Centers for Disease Control and Prevention, CDC Interim Smallpox Response Plan and Guidelines, DRAFT 2.0 (2001) [hereinafter CDC Draft 2.0].

3. Dana Milbank, *Bush Leans To Limited Smallpox Vaccination*, WASHINGTON POST, November 23, 2002, at A01.

4. M. Elizabeth Halloran, et al., *Containing Bioterrorist Smallpox*, 298 SCIENCE 1428, 1428 (2002).

the best scenario. It is in the hope of contributing to the development of such plans that we offer the ideas and observations below.

#### DISTRIBUTION OF VACCINE IN THE CONTEXT OF FEAR

Supplementing the initial CDC interim smallpox response plan is prudent and is a wise step in preparing for response to a terrorist release of the smallpox virus. Although ring vaccination has proven effective in past outbreaks of smallpox,<sup>5</sup> this "proven strategy" is designed for the containment of naturally-occurring outbreaks rather than outbreaks resulting from the release of biological agents in a way that is intentionally designed to maximize their spread, such as simultaneous releases in several large airports.

The initial CDC plan presented six reasons why the ring approach is preferred over "indiscriminate mass vaccination:" 1) ring vaccination without indiscriminate mass vaccination was a successful approach used to eradicate naturally-occurring smallpox; 2) indiscriminate vaccination would lead to higher levels of adverse events, as it would be far more difficult to appropriately screen vaccine recipients for contraindications; 3) currently, there is an insufficient level of available vaccinia immunoglobulin to handle adverse events from vaccination; 4) a rapid depletion of vaccine stores would compromise the ability to address continued outbreaks; 5) mass inoculation efforts would put a severe strain on the public health and health care provider system; and 6) pressure to mass inoculate could lead to panic and negligence in adhering to appropriate disease surveillance and control measures.<sup>6</sup>

Although Bush administration plans seriously consider offering a mass vaccination to the general public on a voluntary basis, many of the reasons for the CDC's initial reliance on ring vaccination (as opposed to mass vaccination) are still salient. For example, a mass vaccination will require a significant public health infrastructure to deal with adverse events from vaccination. In particular, the severe strain on the health care system and likelihood of panic identified in the initial response plan remain problems even under the new mass vaccination guidelines. We have learned from the recent anthrax attacks that public demand for vaccination is likely to be high in the event of a terror-related smallpox outbreak. The anthrax attacks involved an agent far more "containable" than smallpox, and one that unlike smallpox, is not easily spread. Nonetheless, public fear was high, resulting in demand for Cipro and for flu vaccines that threatened avail-

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5. Mark A. Strassburg, *The Global Eradication of Smallpox*, 10 AM. J. OF INFECTION CONTROL 53 (1982).

6. CDC Draft 2.0, *supra* note 2.

ability of these resources for those populations most in need, particularly the elderly. One can imagine, then, the demand for smallpox vaccination that might result from public panic induced by a terror-related outbreak of this highly contagious, deadly disease—a demand highly likely to overwhelm the public health infrastructure. As D.A. Henderson and colleagues describe:

During the smallpox epidemics in the 1960s and 1970s in Europe, there was considerable public alarm whenever outbreaks occurred and, often, a demand for mass vaccination throughout a very widespread area, even when the vaccination coverage of the population was high. In the United States, where few people now have protective levels of immunity, such levels of concern must be anticipated.<sup>7</sup>

The type of demand that Henderson and colleagues describe would simply and utterly overwhelm the health system.<sup>8</sup> The new CDC supplementary guidelines are a first step in addressing these problems. The CDC Smallpox Vaccination Clinic Guide (“Clinic Guide”)<sup>9</sup> offers states a model system through which those seeking vaccination could systematically be moved through the vaccination process.<sup>10</sup> Under this plan, those entering a vaccination clinic would be screened for smallpox symptoms and possible exposure, evaluated and counseled on possible contraindications and questions about the vaccine, informed about potential side effects of the vaccine, and, finally, given the vaccine itself.<sup>11</sup> The guidelines describe staffing needs, activities and vaccination supply distribution plans in the event of a smallpox outbreak.<sup>12</sup> Flow charts, checklists for supply and personnel needs, and example Smallpox Investigational New Drug consent forms are included.<sup>13</sup>

In addition, the Department of Health and Human Services has, as of October 2002, announced plans to hire a clinician with expertise in mass panic situations.<sup>14</sup> This hiring reflects a recognition of the potential for widespread panic and the need for facilitation of clear

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7. Donald A. Henderson et al., *Smallpox as a Biological Weapon*, 281 JAMA 2127, 2133 (1999).

8. MICHAEL OSTERHOLM & JOHN SCHWARTZ, *LIVING TERRORS: WHAT AMERICA NEEDS TO KNOW TO SURVIVE THE COMING BIOTERRORIST CATASTROPHE* xix (2000).

9. Centers for Disease Control and Prevention, *Smallpox Response Plan and Guidelines*, Version 3.0, Annex 3, available at <<http://www.bt.cdc.gov/agent/smallpox/response-plan/index.asp>> (last viewed December 15, 2002) [hereinafter CDC Guidelines].

10. *Id.*

11. *Id.*

12. Centers for Disease Control and Prevention, *Updated Post-Event Smallpox Response Plan and Guidelines*, 288 JAMA 1844 (2002).

13. CDC Guidelines, *supra* note 9.

14. MSNBC, *Smallpox Vaccination Has Risks*, available at <<http://www.msnbc.com/news/821632.asp>> (last viewed December 20, 2002).

communication under such circumstances. Recognition of the likely mass-panic that would result from a bioterror attack is wise, as we discussed above. It also calls, however, for a recognition that orderly approaches to post-event vaccinations are unlikely absent significant planning for a triage of access to vaccination.

Characteristics of smallpox itself and vaccine effectiveness contribute to the likelihood that demand for *immediate* vaccination will be high in the event of a terror-related outbreak. Although the smallpox vaccine can be effective if given up to three to four days after exposure to the virus,<sup>15</sup> smallpox has a latent period of up to two weeks before recognizable symptoms appear,<sup>16</sup> making it difficult to know who has been exposed, which is a problem identified in several simulated scenarios of bioterrorist attacks using smallpox.<sup>17</sup> Since recognizable symptoms do not appear for up to two weeks, in the event of a terror-related outbreak of smallpox, every person must be treated as if potentially exposed, and will likely fear exposure. Of note in this context is an observation drawn from one government exercise that simulated a biological terror attack: of 3878 persons (notionally) seen at one hospital, 3200 of these were “worried well”—persons who did not truly have the disease but were worried that they might be developing it.<sup>18</sup> The two week latency period for smallpox means that effective post-exposure vaccinations would need to occur before recognizable symptoms appear, increasing the likelihood of “worried well” demand for vaccination while simultaneously undermining the ability to distinguish “worried well” from those actually exposed. Since the vaccine is effective only if given up to three to four days after exposure, the difference between receiving the vaccination on day one of mass vaccination and day ten may be significant for some people. Public demand for *immediate* vaccination, then, is highly likely. If a terror-related outbreak does occur, how should we prioritize distribution of the vaccine in a fair, effective, and orderly manner?

Perhaps because the CDC guidelines call for mass vaccination of the entire population in ten days, no triage plans (beyond screening of those already symptomatic or likely exposed) are presented or, presumably, deemed necessary. Lack of such triage planning seems unwise. Although the new guidelines are to be applauded, they seem

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15. Henderson, 281 JAMA at 2132; FRANK FENNER ET AL., *SMALLPOX AND ITS ERADICATION* (1988).

16. Henderson, 281 JAMA at 2132.

17. Tara O'Toole et al., *Shining Light on "Dark Winter,"* 34 CLINICAL INFECTIOUS DISEASES 972 (2002); Jason Bardi, *Aftermath of a Hypothetical Smallpox Disaster,* 5 EMERGING INFECTIOUS DISEASES 547, 547 (1999); Tara O'Toole, *Smallpox: An Attack Scenario,* 5 EMERGING INFECTIOUS DISEASES 540, 540 (1999).

18. Thomas Inglesby et al., *A Plague on Your City: Observations from TOPOFF,* 32 CLINICAL INFECTIOUS DISEASES 436, 441 (2001).

overly optimistic. One study estimated that, assuming vaccination takes approximately ten minutes per patient, 46 million person-hours would be required simply to administer the vaccine to 280 million people.<sup>19</sup> That estimate is probably overly pessimistic for the type of concentrated campaign that would result from a terror-related outbreak. Nevertheless, inoculating 280 million people in ten days is a challenge fraught with potential problems, as we discuss below. Prudence calls for recognition of the possibility that this goal will not be attainable. In short, we should be deeply skeptical of the ability to actually carry out mass vaccination of the entire U.S. population in a ten day period. Although the CDC plan might well work, reliance on this very optimistic scenario is simply unwise. Furthermore, as we also discuss below, *even if this optimistic goal is attainable*, the likely mass fear and panic resulting from a terror-related outbreak of smallpox will require a prioritization plan for the orderly distribution of vaccine.

#### OBSTACLES TO THE EFFECTIVE AND ORDERLY DISTRIBUTION OF VACCINE

Several significant obstacles potentially stand in the way of effective execution of the CDC plan. The plan relies heavily upon large numbers of health care providers—physicians, nurses, physician assistants, emergency medical technicians, even students in the various health professions<sup>20</sup>—making themselves available for service in the vaccination clinics. The CDC estimates that, using this model, vaccination of one million people in ten days would require that a state run twenty vaccination clinic sites for sixteen hours a day.<sup>21</sup> This would require each state to employ personnel totaling 4680, including 800 non-public health security personnel. As part of contingency planning, the Clinic Guide recommends considering increasing these staffing levels by approximately 20%, which would add nearly 1000 additional personnel.<sup>22</sup> Such health care providers would be above and beyond the numbers needed as front line providers of treatment to the symptomatic as well as the exposed, and those still needed to manage essential non-smallpox-related health care responsibilities.

The staffing needs described above would necessitate pre-outbreak vaccination of as many as 510,000 health care professionals.<sup>23</sup> Absent a clearly-defined smallpox threat, it is uncertain that a suffi-

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19. Martin I. Meltzer et al., *Modeling Potential Responses to Smallpox as a Bioterrorist Weapon*, 7 EMERGING INFECTIOUS DISEASES 959, 968 (2001).

20. CDC Guidelines, *supra* note 9.

21. *Id.* at 21.

22. *Id.* at 11.

23. David Brown, *Panel Alters Advice On Smallpox Shots*, WASH. POST, October 17, 2002, at A03.

cient supply of health care providers will be willing to risk their health and livelihoods in order to receive pre-outbreak vaccination.<sup>24</sup> Although pre-event vaccination is likely to be in high demand among a fearful general population, this may not be the case among better-informed healthcare professionals. A number of medical associations, including the American Medical Association, the American Academy of Family Physicians, and the American Academy of Pediatricians, have expressed concerns about the recommendation of a nationwide pre-event smallpox vaccination plan, based in part on the recognized serious side effects of the smallpox vaccine.<sup>25</sup> Health care providers also express concern about the impact of pre-outbreak vaccination of physicians and nurses on already-strained hospital staffing levels.<sup>26</sup> A number of large hospitals in Atlanta, Philadelphia, as well as nine of Colorado's twelve largest hospitals, among others, have publicly announced their intention to not vaccinate their employees.<sup>27</sup>

This is significant because vaccination of health care providers could lead to critical delays in commencement of public vaccination. As stated in the Clinic Guide, "[e]stablishment of voluntary clinics may need to be done in a stepwise fashion over two to three days to accommodate the administration of staff vaccinations prior to opening a clinic."<sup>28</sup> Working at maximum efficiency and full capacity without slowdowns due to panic or supply problems, the plan estimates that each of a clinic's eight vaccination stations would administer between thirty-five and forty-five vaccinations each hour.<sup>29</sup> Barring any wane in speed or efficiency over a two-shift, sixteen hour day, each clinic would administer approximately 5780 shots per day.<sup>30</sup> To achieve the stated goal of administering 280 million vaccinations in a ten day period would require the states collectively to set up and run 4844 clinics (a number roughly equivalent to the number of community hospitals in the United States)<sup>31</sup> at full staffing levels and maximum public ca-

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24. Marie McCollough, *Smallpox strategy hits snag in U.S.*, PHILADELPHIA INQUIRER, December 8, 2002, at A01.

25. Denise Grady, *Doctors Urge Caution on Smallpox Vaccinations*, N.Y. TIMES, October 8 2002, at A16.

26. Anne Barnard, *Doctors, Nurses Raise Concerns Over Smallpox Plan*, BOSTON GLOBE, September 25, 2002, at B4.

27. Allison Sherry, *Smallpox Shots Spur Fears*, DENVER POST, January 8, 2003, at A1.

28. CDC Guidelines, *supra* note 9.

29. *Id.*

30. *Id.*

31. Centers for Disease Control and Prevention, National Center for Health Statistics, Health, United States, 2002, Table 107. Hospitals, beds, and occupancy rates, according to type of ownership and size of hospital: United States, selected years 1975-2000, available at <http://www.cdc.gov/nchs-products/pubs/pubd/hs/tables/2002/02hus107.pdf> (last viewed December 15, 2002).

capacity. As the Maryland Secretary of Health has pointed out, the “idealized guidelines” (which he believes offer a five-fold underestimate of the number of necessary vaccine clinic workers) do not even take into account the hurdles and delays of routine vaccination: elderly people bundled in layers of clothing, some elderly people in wheelchairs, patients who do not speak English, or patients who have complicated medical histories.<sup>32</sup>

In addition to problems concerning staffing and clinic efficiency, significant logistical problems are possible, perhaps probable. The “TOPOFF” exercise conducted in May 2000 offers insight into the nature of such problems.<sup>33</sup> TOPOFF was a Department of Justice-coordinated readiness exercise engaging key government personnel in simulated chemical, biological and cyberterrorist attacks.<sup>34</sup> The bioterror attack simulation involved a four-day drill following the aerosol release of *Yersinia pestis* (plague) in Denver, Colorado.<sup>35</sup> In the course of that exercise, significant breakdowns occurred. Resources from the National Pharmaceutical Stockpile which were flown in to Denver International Airport could not smoothly be transported from the airport to the treatment and prophylaxis delivery sites.<sup>36</sup> Material delivered to the airport for the purposes of the drill was delayed by the fact that only a single individual had been assigned to count pills and place them in baggies for distribution, and even this was delayed for six hours by difficulties in getting baggies from a local Safeway store.<sup>37</sup> When finally delivered to central antibiotic “points of distribution,” the distribution process was so unmanageable that only 140 people an hour could receive the medication.<sup>38</sup>

The process of designating specific locations at which to receive antibiotics also proved troublesome; hospitals, attempting to handle caseloads ten times their normal capacities, and to control crowds outside their doors while containing potentially infected patients within their facilities, rapidly found themselves overwhelmed.<sup>39</sup> Hospitals and communities also found themselves competing for assistance and guidance from federal and state officials.<sup>40</sup> Language and communication hurdles such as the use of different terminology and decision-making processes by different parties involved in the coordi-

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32. Ceci Connolly, *Volunteers Key to Smallpox Vaccine Plan* WASH. POST, September 24 2002, at A02.

33. Inglesby, 32 *CLINICAL INFECTIOUS DISEASES* at 436.

34. *Id.*

35. *Id.* at 437.

36. *Id.* at 440.

37. *Id.*

38. *Id.*

39. *Id.* at 441.

40. *Id.*

nation efforts also hindered consensus building and speed of response.<sup>41</sup>

Problems encountered in the TOPOFF exercise are likely to be even greater in an actual emergency. According to Inglesby *et al.*, Denver was chosen “in part because it had received domestic preparedness training and equipment.”<sup>42</sup> In addition, while the intent of the exercise was to run a “no notice” drill concerning the nature of the bioterror attack and the event’s timing, some federal and state health officials “did have knowledge or a strong suspicion that the exercise would feature a plague outbreak and that it would begin on the day it did, which allowed them to review the medical and public health implications of plague infection in anticipation of the event.”<sup>43</sup> We should expect, then, that in the event of an actual “surprise” biological attack, there will be even greater logistical, communication, and distribution problems.

Even if vaccination of the entire population can be accomplished in a ten day period, triage will likely be necessary to bring any semblance of order to the distribution of the vaccine. As we discussed earlier,<sup>44</sup> the fact that recognizable symptoms of smallpox do not appear for up to two weeks, along with the need to receive vaccination within three to four days of exposure for the vaccine to be effective, will make one’s “place in line” for vaccination significant in some cases. Given the public panic that must be assumed in the wake of a terror-related outbreak of smallpox, chaos in demand for immediate (day one) vaccination is likely in the absence of a clear, understandable, and publicized plan for triage of access to vaccination, even in the best case scenario of accomplishing mass vaccination of the entire population in ten days.

#### THE NEED FOR FURTHER PLANNING

In his proposed 2003 budget, President Bush requested \$5.9 billion for defense against biological attack, including \$1.2 billion to improve state and local health delivery response systems, \$2.4 billion in bioterrorism research and development, \$851 million to improve federal response capabilities, \$100 million of which is allocated “to improve our ability to distribute and effectively use the nation’s supply of smallpox vaccine,” and \$392 million to improve communications in re-

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41. *Id.* at 440.

42. *Id.* at 436.

43. *Id.* at 437.

44. See *supra* notes 15-17 and accompanying text.

sponse to a biological attack.<sup>45</sup> Devoting resources to the strengthening of the public health infrastructure is a necessary first step,<sup>46</sup> one that should provide benefits for response to attacks using other potential biological agents, as well as non-bioterrorism related public health benefits.<sup>47</sup> It is unrealistic, however, to expect that we soon will be able to build a public health infrastructure able to overcome the practical difficulties involved in the mass distribution of a vaccine to over 280 million people.

Accordingly, we must plan now for a triage of resources in the event of a bioterrorism attack resulting in an uncontrollable outbreak of smallpox. The plan must use the basic principles of triage to ensure the most effective and fair distribution of the smallpox vaccine in an emergency scenario. It must be consistent with political boundaries for both state and healthcare professional intervention.<sup>48</sup> It must also seek input from the medical community to determine appropriate criteria for possible triage and the limitations of these criteria. The reasons for adopting these criteria must be understood and accepted by the public.

The basic principles of triage distribute resources after categorizing potential recipients of treatment into three general groups: 1) those that will likely die without immediate treatment but are likely to survive with treatment; 2) those that will suffer without immediate treatment but likely will not die; and 3) those for whom treatment will likely provide no benefit or will have a very minimal benefit.<sup>49</sup> Those in the first group receive resources first, followed by the second group, and finally the third.<sup>50</sup> Smallpox results in death for approximately 30% of those who contract the disease<sup>51</sup> and there is no effective treatment once the disease is contracted; the only treatment is to be vaccinated.<sup>52</sup> However, there is no way to know who will die and who will survive if they contract smallpox. On the surface, then, we must treat

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45. Executive Office of the President, Office of Management and Budget, 2002. Budget of the United States Government Fiscal Year 2003, 18-19 (2003), available at <http://www.whitehouse.gov/omb/budget/fy2003/pdf/bud05.pdf> (last viewed November 1, 2002).

46. Department of Health and Human Services, Office of Inspector General, Report #OEI-02-01-00550, State and Local Bioterrorism Preparedness (December 2002).

47. *Id.*

48. THOMAS MAY, BIOETHICS IN A LIBERAL SOCIETY: THE POLITICAL FRAMEWORK OF BIOETHICS DECISION MAKING 22-31, 81-97 (2002).

49. GERALD WINSLOW, TRIAGE AND JUSTICE 1, 63-70, 94 (1982).

50. *Id.*

51. Henderson, 281 JAMA at 2133. This estimates the morbidity arising from naturally occurring *Variola major*, as opposed to a genetically-modified strain of smallpox that might have greater morbidity and resistance to Western vaccines. *Id.* See, e.g., RICHARD PRESTON, THE DEMON IN THE FREEZER (2002).

52. FENNER, *supra* note 15, at 68.

every individual as if they fall into the group that will likely die if they are not vaccinated and ultimately contract the disease (the first triage group).

In the case of smallpox, however, there is potentially a way to identify a segment of the population that might be categorized into the second triage group; those who have been previously vaccinated. Routine vaccination for smallpox was discontinued in the U.S. in the early 1970s.<sup>53</sup> However, a large segment of the current U.S. population received the smallpox vaccination before it was discontinued.<sup>54</sup> Because the effectiveness of the smallpox vaccine diminishes over time,<sup>55</sup> it is believed that vaccination prior to the early 1970s discontinuation is unlikely to provide protection from contracting smallpox. However, evidence exists that some immunity may linger for thirty years or more after vaccination,<sup>56</sup> resulting in less severe cases of smallpox for those who were previously vaccinated, and that members of this segment of the population are far less likely to die should they contract the disease.<sup>57</sup> This is a phenomenon that has been widely neglected; while it is true that the belief that “those vaccinated against smallpox prior to discontinuation will not retain immunity” should be our first focus in emphasizing the need to re-vaccinate this segment of the population as quickly as possible in the event of a bioterror attack, it may be equally important to recognize the less severe nature of smallpox cases for this segment of the population so that an effective triage plan might be developed should a mass vaccination effort be necessary.

Furthermore, those receiving re-vaccination have both an accelerated development of neutralizing antibody (on average three days shorter) and stronger immune response to smallpox compared to those receiving vaccination for the first time.<sup>58</sup> According to Fenner *et al.*:

Following primary vaccination, no antibody was detected up to the 10th day, after which neutralizing and HI antibodies were present in the majority of individuals and CF antibodies in less than half. . . . Neutralizing antibodies were clearly much the most persistent, sometimes being demonstrable for more than 20 years after primary vaccination. . . . In revac-

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53. Henderson, 281 JAMA at 2131.

54. *Id.*

55. FENNER, *supra* note 15, at 53.

56. Jeffrey A. Frelinger & Mohammed L. Garba, *Responses to Smallpox Vaccine*, 347 NEW ENG. J. MED. 689 (2002); Walter E. Demkowicz, Jr. et al., *Human Cytotoxic T-cell Memory: Long-Lived Responses to Vaccinia Virus*, 70 JOURNAL OF VIROLOGY 2627, 2627 (1996); FENNER, *supra* note 15, at 158; K. McCarthy et al., *The antibody response in man following infection with viruses of the pox group. II. Antibody response following vaccination*, 56 JOURNAL OF HYGIENE 466, 477 (1958).

57. MELTZER, 7 EMERGING INFECTIOUS DISEASES at 959; Demkowicz, Jr., JOURNAL OF VIROLOGY at 154.

58. FENNER, *supra* note 15, at 158.

cinated individuals (several of whom possessed neutralizing antibodies before revaccination), the antibody titres tended to be higher, and when a response occurred, it began earlier, often within 7 days. . . . The accelerated immune response in revaccination (within a week, compared with over 10 days in primary vaccination) was of considerable importance in protecting persons by vaccination after exposure to smallpox.”<sup>59</sup>

Quicker antibody-producing responses from those who have been previously vaccinated might make it less crucial that they be vaccinated immediately.

In short, those vaccinated against smallpox prior to the discontinuation of this routine vaccination are likely susceptible to contracting the disease if exposed to the smallpox virus and will likely become very sick, but are likely to experience less severe cases of the disease and thus are less likely to die if they contract the disease. They seem to experience a quicker response in producing antibodies when re-vaccinated *compared to those receiving vaccination for the first time*. This phenomenon results in characteristics that potentially enable us to categorize those vaccinated against smallpox prior to discontinuation of routine vaccination in the second triage group. Fortunately, the likelihood that prior vaccination was effective (at the time of vaccination) is easily identifiable by the presence of a scar where the vaccine was administered—a sign that the vaccine “took.” While we should continue to strive to provide new vaccinations to this group as quickly as possible in the event of an outbreak, our first distribution efforts should be directed at those most likely to suffer the most severe and preventable consequences from contracting smallpox.

It is important to note that the information we describe above is speculative. Because smallpox had been eliminated at the time routine vaccination was discontinued, there is no large-scale data available for the effectiveness of a smallpox vaccination long-term, nor is there any level of protections provided by distant vaccination. Nonetheless, the information cited reflects the best estimates concerning protections. We know *for certain* that no protection exists for those who have never been vaccinated. Since the never-vaccinated are known to have no protection whatsoever against smallpox and the once-vaccinated are thought to have *some* level of protection and quicker antibody responses resulting in likely less severe cases, it should be the former group that receives first access to vaccination in circumstances where some form of prioritization is necessary. Triage demands that best estimates be made as to potential outcomes for identifiable groups.

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59. *Id.* at 158-59.

Ideally, distribution would occur to every person simultaneously. In reality, this is simply impossible, (even under the best scenario imaginable). Some people, then, will have later access to the vaccination than others, regardless of which plan we adopt. The criteria for prioritizing access, then, should identify those groups likely to be most negatively affected if access is delayed and those groups whose delayed access may result in negative effects (but effects less severe than are likely to be experienced by others). It is this type of criteria our proposal seeks to offer.

Triage based on such criteria is merely a first step. Further questions remain: for example, how do we ensure that the order of priority is followed? How do we distribute vaccination evenly between clinic sites? Should some populations, such as the families of healthcare workers, or previously vaccinated parents who bring unvaccinated children to a vaccination clinic site, be exempted from the broader triage grouping? A full triage plan would need further criteria to prioritize groups into manageable segments, distributed between vaccination sites. Furthermore, additional concerns about implementation and enforcement would remain should anything less than nationwide adoption of a triage plan occur, e.g., volume overload risks due to adverse selection for states electing not to implement a comprehensive triage plan.

In addition, there simply is no viable way to ensure that *everyone* will follow the priority guidelines we outline. It makes no sense, in the context of the primary goal of streamlining the vaccine distribution process, to add yet another layer of bureaucracy to screen those who have been previously vaccinated. We must rely on the conscientiousness of the public in waiting their turn in priority. While panic is likely in the absence of clear, publicized plans for distribution of the vaccine, concerted public education about *the reasons for* the order of priority—namely, the expected less severe risks, and quicker antibody response, for those who have been previously vaccinated—should go a long way toward alleviating panic and encouraging compliance with the plan.

Nonetheless, there can be no doubt that many will attempt to “cut in line.” Triage at the level at which our plan would be implemented, however, is concerned with initial divisions among large segments of the population. While there are no concrete numbers that indicate how many people have been vaccinated against smallpox, the 2000 U.S. Census indicates that 44% of the population was born in 1970 or later.<sup>60</sup> It should be safe to assume, then, that a high proportion of

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60. U.S. Census Bureau, 2000 Census, PCT12: SEX BY AGE [209]—Universe: Total Population, *available at* [http://factfinder.census.gov/servlet/DTTable?ds\\_name+](http://factfinder.census.gov/servlet/DTTable?ds_name+)

the remaining 56% of the population has been vaccinated. In fact, this number is consistent with a Harvard School of Public Health/Robert Wood Johnson Foundation survey, in which 56% of respondents indicated that they had been vaccinated against smallpox.<sup>61</sup> If even half of those who were previously vaccinated were willing to respect the priority ordering of our publicized triage plan, we will have been successful in reducing initial (day one) demand for vaccination by approximately one-third of the population. This is far better than the unmitigated “stampede” that would likely result on day one in the absence of a clear, publicized triage plan. Furthermore, the public can self-identify for prior vaccination through the existence of the well-known scar (usually on the shoulder), eliminating the need to devote scarce personnel or add layers of bureaucratic procedure to divide this segment of the population.

Distribution to those who will receive the vaccination into manageable segments of the population at several locations is another important problem. One lesson from TOPOFF is that under the Vaccine Clinic plan, it is unlikely that the population response would be so uniform as to ensure that some or many of the clinics would not be overwhelmed by receiving a disproportional share of the patient volume, even in a city with “ample” clinic capacity to serve the local population.<sup>62</sup> One method that might be used to address this is to take the vaccination to certain identifiable segments of the population that fall into the first triage group. For example, as the routine vaccination for smallpox was discontinued in the early 1970s, the approximately 59 million children in the United States of school age are unvaccinated and therefore fall into the first priority group.<sup>63</sup> Vaccinating children *at school* would provide a way to distribute demand away from clinic locations and would have the further benefit of eliminating the problem of deciding whether to vaccinate previously vaccinated parents of unvaccinated children, were these parents required to bring their children to a clinic.

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DEC\_2000\_SF1\_U&geo\_id=01000US&mt\_name=DEC\_2000\_SF1\_U\_PCT012but (last viewed on November 17, 2002). This data is used to approximate the size of the population born between 1972, the year in which routine vaccination ended, and 2002.

61. Robert J. Blendon et al., *Study 3: Public Attitudes About the Threat of a Smallpox Attack*, at 11, Harvard School of Public Health, Robert Wood Johnson Foundation, Survey Project on Americans' Response to Biological Terrorism, available at <http://www.hsph.harvard.edu/press/releases/smallpox/-topline.doc> (last viewed December 15, 2002).

62. Inglesby, 32 CLINICAL INFECTIOUS DISEASES at 441.

63. U.S. Census Bureau, *supra* note 60. This number represents the total number of school-aged children (5-18) in the 2000 Census, which would, of course, vary slightly from 2002 Census estimates.

Of course, several issues would need to be addressed before a school-based vaccination program could be employed, including issues concerning consent,<sup>64</sup> screening, and the administration of the vaccine without parents present. These obstacles, however, should be able to be overcome. School-based vaccination programs have been successfully employed as part of comprehensive childhood immunization strategies, both under emergent, post-outbreak<sup>65</sup> and non-emergent conditions.<sup>66</sup> These programs, while significantly more modest in scope, along with the use of personnel and resources and with lower inherent risks than in a smallpox vaccination program, may serve as a useful model for a school-based emergent smallpox response plan.

This plan would not offer complete coverage for the school-aged population. For example, students who are home-schooled or absent from school might not receive vaccination under such a plan. However, the primary objective here is to divide priority among large segments of the population, thereby reducing the potentially overwhelming initial demand for vaccination in the aftermath of a bioterror attack, rather than to account for potential "outliers." We also recognize that a school-based vaccination program would require additional personnel to administer vaccinations. Given the likely staffing shortages we have already described, this may not be feasible. However, a post-event mass vaccination plan must include significant efforts to distribute the population as evenly as possible between vaccination sites, as we have discussed. Taking personnel from clinic sites, then, to administer the vaccination to this segment of the population, all of whom fall into the first priority group in addition to the special priority normally given to children by society, may be justified.

All of the proposals we offer above must be subjected to further study and evaluation. Our observations are meant to highlight the need for further planning beyond that already undertaken. Biological terror attacks pose a grave danger to the U.S. population, particularly if such attacks involve agents that, like smallpox, are highly contagious and thus easily spread. It is not enough to simply stockpile re-

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64. American Academy of Pediatrics, *Informed Consent, Parental Permission, and Assent in Pediatric Practice (RE9510)*, 95 PEDIATRICS 314 (1995).

65. Susan Hall et al., *The Use of School-Based Vaccination Clinics to Control Varicella Outbreaks in Two Schools*, 105 PEDIATRICS e17 (2000), available at <<http://www.pediatrics.org/cgi/content/full/105/1/e17>> (last viewed November 15, 2002).

66. Thad Wilson, *Economic Evaluation of a Metropolitan-Wide, School-Based Hepatitis B Vaccination Program*, 17 PUBLIC HEALTH NURSING 222 (2000); Robert Deuson, *The Denver School-Based Adolescent Hepatitis B Vaccination Program: A Cost Analysis With Risk Simulation*, 89 AM. J. PUBLIC HEALTH 1722, 1722 (1999); Murray Krahn et al., *Costs and Cost-Effectiveness of a Universal, School-Based Hepatitis B Vaccination Program*, 88 AM. J. PUBLIC HEALTH 1638, 1638 (1998); S. Dobson et al., *Assessment of a Universal, School-Based Hepatitis B Vaccination Program*, 274 JAMA 1209, 1209 (1995).

sources for such attacks; we must also devise strategies for distributing these resources in a fair and effective manner. While immediate distribution to every individual is a laudable ideal, it is not a reasonable expectation in an emergency situation, particularly one which is likely to induce panic and demand for immediate access to resources. We should continue to work toward as quick a distribution of resources to all groups as possible, but also must recognize limitations in our capacity to immediately distribute resources nationwide, and to identify those groups in gravest danger so we can devote our first efforts toward them. We hope the plan we describe above will foster discussion of how an effective and fair triage plan might be formulated using current medical knowledge, with input from medical, public health and government officials, as well as the public at large.