Journal of Health Care Law and Policy

Volume 8 | Issue 1 Article 7

Some Right Jabs and Back in the Ring: Lessons Learned from the Phase I Civilian Smallpox Program

Elin Gursky

Avani Parikh

SOME RIGHT JABS AND BACK IN THE RING

LESSONS LEARNED FROM THE PHASE I CIVILIAN SMALLPOX PROGRAM

ELIN GURSKY AND AVANI PARIKH*

I. THE SUCCESSES WROUGHT FROM VACCINATION

With the exception of providing safe drinking water, nothing, including the development of antibiotics, has had a more positive effect on reducing death and improving the health status of populations globally than vaccines. Since 1900, the average lifespan of persons in the United States has been lengthened by more than thirty years: twenty-five years of this gain are attributed to advances in public health in which vaccination is the leading achievement.[1] The twentieth century began with the development of five vaccines; by the end of that century, twenty-one additional diseases had been deemed largely "vaccine preventable."[2]

The process of vaccination takes advantage of the body's immune system, which is responsible for attacking invading disease-causing microbes.[3] Vaccination enhances the immune system through the introduction or injection of live (weakened or attenuated infectious agents) or inactivated (non-infectious or killed agents) proteins of infectious organisms.[4] When challenged by a specific

---

* Elin Gursky, Sc.D. is Principal Deputy for Biodefense, National Strategies Support Directorate at Analytic Services, Inc. (ANSER). Avani Parikh is a second year student in the MD/MPH program at the University of Texas and a served as an intern analyst at ANSER from May to July 2004.

1. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC), U.S. DEP'T OF HEALTH AND HUMAN SERVS. (DHHS), TEN GREAT PUBLIC HEALTH ACHIEVEMENTS – UNITED STATES, 1900-1999, 48 MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR) 241 (April 2, 1999) [hereinafter MMWR WEEKLY] (citing John P. Bunker et al., *Improving Health: Measuring Effects of Medical Care*, 72 MILBANK Q. 225 (1994)).

2. *See* CDC OFFICE OF COMMUNICATION, DHHS, IMPACT OF VACCINATIONS UNIVERSALLY RECOMMENDED FOR CHILDREN (April 2, 1999), http://www.cdc.gov/od/oc/media/mmwrnews/n990402.htm#mmwr2 (last visited Feb. 20, 2005) (noting that "21 diseases have been added to the list of those which are preventable by vaccine"). Every vaccine has a small failure rate that can vary levels of efficacy. No vaccine has a 100% efficacy across the entirety of the target population. Helen Bedford & David Elliman, *Concerns About Immunisation*, 320 BRIT. MED. J. 240 (Jan. 22, 2000), http://www.whale.to/m/elliman9.html (last visited Feb. 20, 2005).

3. NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, DHHS, UNDERSTANDING VACCINES: WHAT THEY ARE, HOW THEY WORK 2 (Nat'l Inst. of Health (NIH) Publ'n No. 03-4219, July 2003), http://www.niaid.nih.gov/publications/vaccine/pdf/undvacc.pdf (last visited Feb. 20, 2005) [hereinafter UNDERSTANDING VACCINES].

4. *See id.* at 20-22 (describing the properties of both attenuated and inactivated vaccines).

microbe, the healthy and vaccinated immune system mounts a quick protective response to prevent or reduce the effects of the disease.[5]

In fact, the history of vaccination can be traced to smallpox, an utterly disfiguring disease in the approximately 60% of individuals who survived their infections.[6] In the late eighteenth century, Dr. Edward Jenner noticed that milkmaids retained their unblemished, pox-free complexions when stricken with cowpox, a far less severe but related form of the smallpox virus.[7] Furthermore, having once contracted cowpox, the milkmaids seemed to be protected from subsequently catching smallpox.[8] In 1796, Jenner tested that theory by deliberately infecting an eight-year old boy with the pus from a cowpox lesion or sore.[9] The boy became ill with cowpox but recovered, after which time Jenner infected this child with the causative agent of smallpox, the variola virus.[10] As predicted, the earlier infection with the cowpox prevented the boy from catching smallpox. By 1801, one hundred thousand people had been "vaccinated."[11]

The history of disease elimination and reduction can be recounted through the successes in vaccine development. Vaccines have removed from today's consciousness the intractable cough of pertussis, the writhing and delirium-associated death from rabies, and the confinement within an iron lung of polio victims.[12] In the present day, by the time children are two years of age in most industrialized countries they have had several series of shots to protect them from diseases including measles, mumps, rubella, polio, diphtheria, pertussis, tetanus, Hepatitis B, and varicella.[13]

There have been many key milestones in vaccine development since the time of Jenner that have capitalized upon the efforts of dedicated research scientists, the expanding knowledge of the human immune system, and, most recently, evolving biotechnologies. In 1885, Louis Pasteur sparked major controversy by injecting live rabies vaccine into two people.[14] A killed rabies vaccine developed in 1964 that required up to thirty painful shots in the abdomen was replaced 100 years after

---

5. *Id.* at 3.

6. DAVID PERLIN & ANN COHEN, THE COMPLETE IDIOT'S GUIDE TO DANGEROUS DISEASES AND EPIDEMICS 67 (2002).

7. UNDERSTANDING VACCINES, *supra* note 3, at 9.

8. *Id.*

9. *Id.*

10. *See* UNDERSTANDING VACCINES, *supra* note 3, at 9, 10.

11. STEVEN LEHRER, EXPLORERS OF THE BODY, ch. 8 (1979).

12. *See* UNDERSTANDING VACCINES, *supra* note 3, at 2.

13. *E.g.*, NAT'L IMMUNIZATION PROGRAM (NIP), DHHS, RECOMMENDED CHILDHOOD AND ADOLESCENT IMMUNIZATION SCHEDULE – UNITED STATES (July – December 2004), http://www.cdc.gov/nip/recs/child-schedule-jul-dec-rev.pdf (last visited Feb. 20, 2005).

14. KidsGrowth, *A Short History of Vaccine Development* (1999), *at* http://www.kidsgrowth.com/resources/articledetail.cfm?id=1372 (last visited Feb. 20, 2005) [hereinafter KidsGrowth].

Pasteur's work by a new vaccine that involved only five shots in the arm.[15] Killed vaccines were developed in 1896 for cholera and typhoid, in 1897 for plague, and in 1926 for pertussis ("whooping cough").[16] In 1923, a powerful toxin from diphtheria was chemically inactivated as a toxin to kill the bacteria.[17] In 1927, the development of a tetanus vaccine reduced the number of cases per year from 600 to seventy and the number of deaths from 180 to fifteen.[18] Vaccines were "combined" by the 1940's to provide the childhood DTP vaccination (diphtheria, tetanus and pertussis).[19] Before the development of the diphtheria vaccine there were as many as 200,000 cases and 15,000 deaths: there were only four deaths in children from diphtheria between 1980 and 1995.[20] DTaP, a combination of diphtheria, tetanus and pertussis in its "accellular" form (meaning composed of only specific fragments – not the whole – of bacterial cells best suited to stimulating a strong immune response with reduced adverse reactions), was approved in 1996.[21] Annual pertussis deaths have dropped from 8,000 before the vaccine to only about 10 today as a result of this new vaccine.[22]

Alfred Sabin developed a live oral polio vaccine in 1961.[23] Since the adoption of the 1998 World Health Assembly poliomyelitis eradication initiative, there has been a greater than 99% reduction in reported cases.[24] By 1963, a safe and effective vaccine for measles, one of the most infectious diseases, had been developed, profoundly reducing the number of cases from 4 million with 3,000 deaths in 1962 to 309 with no deaths in 1995.[25] A live, attenuated measles virus vaccine was disseminated to several parts of the world in the late 1970s, and by 1990 global measles vaccine covered approximately 70% of children aged two

15. *Id.*

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. *Id.*; NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES (NIAID), DHHS, IMPROVED PERTUSSIS VACCINES: ENHANCING PROTECTION, *at* http://www.niaid.nih.gov/publications/discovery/pertus.htm (last visited Feb. 20, 2005) [hereinafter IMPROVED PERTUSSIS VACCINES].

21. CDC, DHHS, PERTUSSIS VACCINATION: USE OF ACELLULAR PERTUSSIS VACCINES AMONG INFANTS AND YOUNG CHILDREN RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP), 46 MMWR (March 28, 1997), http:/www.cdc.gov/epo/mmwr/preview/mmwrhtml/00048610.htm (last visited Feb. 20, 2005). *See also* IMPROVED PERTUSSIS VACCINES, *supra* note 20.

22. KidsGrowth, *supra* note 14.

23. *Id.* INSTITUTE OF MEDICINE, ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY 188 (Kathleen R. Stratton et al. eds., 1994).

24. Daniel Tarantola, *Polio: Present Status and Post-Eradication Policies; in* VACCINES: PREVENTING DISEASE & PROTECTING HEALTH 23 (Ciro A. de Quadros ed., 2004).

25. KidsGrowth, *supra* note 14.

years.[26] According to the WHO, measles remains responsible for ten percent of deaths in children under five years of age worldwide.[27] A vaccine for mumps licensed in 1967 reduced the incidence of the disease from 200,000 annual cases with thirty deaths to only 600 cases with no deaths.[28] By 1970, several strains of rubella had been weakened to make a vaccine.[29] Between 1964 and 1965, 20,000 children suffered birth defects, the result of about 12 million cases of rubella.[30] Today, there are only about five cases of birth defects per year.[31] The vaccines for measles, mumps, and rubella have been combined into one vaccine known as "MMR."[32]

The meningococcal, pneumococcal and haemophilus influenza type b (Hib) vaccines were developed through the 1970's and 1980's, protecting the human population against life-threatening diseases such as meningitis, blood infections, and some pneumonias.[33] A vaccine for Hepatitis B was officially licensed in 1986 that contained an antigen that is *cloned* rather than *grown*.[34] A killed vaccine for Hepatitis A was developed in 1995.[35] In the year 2000, influenza vaccine use reached 70 million doses, an important step in reducing the almost 20,000 premature deaths annually from this disease.[36] Today, researchers are working to improve the safety and efficacy of existing vaccines, such as smallpox, and are searching for new vaccines to fight such deadly diseases as HIV/AIDS, which is expected to kill 70 million people by 2020,[37] and many cancers.[38]

Worldwide, immunization can be credited with saving approximately 9 million lives each year.[39] As many as an additional 16 million deaths each year

---

26. Ciro A. de Quadros, *Is Global Measles Eradication Feasible?, in* VACCINES: PREVENTING DISEASE & PROTECTING HEALTH *supra* note 24, at 35.

27. *Id.*

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. INSTITUTE OF MEDICINE, *supra* note 23, at 121.

33. *Id.* at 236-38; KidsGrowth, *supra* note 14.

34. INSTITUTE OF MEDICINE, *supra* note 23 at 212-13.

35. Anthony E. Fiore, *Hepatitis A Transmitted by Food,* 38 CLIN. INFECTIOUS DISEASE 705, 710 (2004), http://www.cdc.gov/ncidod/diseases/hepatitis/a/fiore_ha_transmitted_by_food.pdf (last visited Feb. 20, 2005).

36. KidsGrowth, *supra* note 14.

37. Anthony S. Fauci, *Vaccines and the Challenge of Emerging and Re-Emerging Diseases: From HIV/AIDS to Bioterrorism, in* VACCINES: PREVENTING DISEASE & PROTECTING HEALTH, supra note 24, at 7.

38. Margaret I. Johnston & Jorge Flores, *Progress in HIV Vaccine Development,* 1 CURRENT OP. IN PHARMACOLOGY 504 (2001), http://www.niaid.nih.gov/daids/vaccine/pdf/pc1506.pdf (last visited Feb. 20, 2005).

39. UNITED NATIONS INTERNATIONAL CHILDREN'S EMERGENCY FUND (UNICEF), VACCINES BRING 7 DISEASES UNDER CONTROL, 4TH ANNUAL REPORT ON THE PROGRESS OF NATIONS (1996), http://www.unicef.org/pon96/hevaccin.htm (last visited Feb. 20, 2005).

could be prevented if effective vaccines were used against all potentially vaccine-preventable diseases.[40] Achieving high levels of disease protection within populations is not just a matter of vaccine *development*, but also one of vaccination *systems* that assure vaccine supply, routine access to health care, and a medical and public health infrastructure capable of administering scheduled immunizations on schedule.[41]

The problems associated with implementing robust vaccination systems are not unique to developing countries. Each year across pockets of this country numbers of young children are barred from school entry because they have not received their routinely scheduled immunizations.[42] One such example is the District of Columbia, where over 5,500 children were lacking required immunizations when classes resumed in 2002.[43] As parents were contacted and thousands of students were not allowed to start school, the media noted that this was a "recurring problem that kept many children out of class [in the previous] year."[44]

There is a constant challenge to ensuring that new birth cohorts receive multiple series of vaccines on schedule. The National Immunization Survey of children nineteen to thirty-five months old determined that coverage for recommended vaccines (DTP or DT or DtaP, poliovirus, measles, Hib, Hepatitis B) was greater in 2003 than in 2002, representing a range in states from 94.0% in Connecticut to 67.5% in Colorado, and among urban areas of 88.8% (Boston) to 69.2% (Houston).[45] Among children entering kindergarten and first grade in the 2003-2004 school year, a "safety net" for childhood immunization, coverage for all vaccines except varicella (chicken pox) was at 95% nationally.[46]

Mass immunization campaigns remain a valuable public health tool for seasonal vaccination activities (such as annual influenza vaccination),[47] for

---

40. *Id.*

41. *See* MMWR WEEKLY, *supra* note 1, at 247 (describing certain infrastructural problems concerning successful vaccination programs).

42. *E.g.*, Sewell Chan, *District Resorts to Court To Enforce Inoculations; 434 Students' Parents May Face Neglect Charges*, WASH. POST, Oct. 2, 2004, at B4, *available at* 2004 WL 93180554 (noting that children who had not been vaccinated prior to the beginning of school were barred from entry).

43. Justin Blum, *5,500 in DC Still Lack Vaccination; Classes Resume for Most While Parents of Those Lacking Shots are Contacted*, WASH. POST, Sept. 4, 2002, at B1, *available at* 2002 WL 26000715.

44. *Id.*

45. CDC, DHHS, National, State, and Urban Area Vaccination Coverage Among Children Aged 19 – 35 Months, 53 MMWR 658 (July 30, 2004), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5329a3.htm (Feb. 2, 2005).

46. CDC, DHHS, Vaccination Coverage Among Children Entering School – United States, 2003-04 School Year, 53 MMWR 1041 (Nov. 12, 2004), http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5344a4.htm (last visited Feb. 20, 2005).

47. *See* NIP, DHHS, INACTIVATED INFLUENZA VACCINE: WHAT YOU NEED TO KNOW, 2004-2005 (May 24, 2004), http://www.cdc.gov/nip/publications/VIS/vis-flu.pdf (last visited Feb. 20, 2005).

outbreak control (such as administering Immune Globulin after exposure to Hepatitis A),[48] or for rapidly instituting age-specific "catch up" (such as immunizing a large cohort of five-year olds prior to the start of school in September).[49] Groups like the World Health Organization (WHO), the World Bank, and the Gates Foundation are actively supporting global initiatives to help reduce morbidity and mortality from vaccine-preventable diseases in developing countries.[50] For example, WHO is fighting meningitis through mass vaccination programs in Chad, Ethiopia, Gambia, and many other regions in Africa that are considered the African Meningitis Belt.[51]

For individuals with access to consistent health care, vaccinations are a critical component of assuring wellness throughout their lifespans, from infants to adults to seniors. Many states had already required citizens to submit to vaccination for smallpox and other diseases at the time when the responsibility of governments to impose immunization requirements upon its citizens was challenged in the 1905 United States Supreme Court case, *Jacobson v. Massachusetts*.[52] The cost-effectiveness of vaccinations and their value as a social good has resulted in vaccination becoming generally compulsory for school entry, employment, and international travel.[53] Early school vaccination policies were coupled with compulsory education laws and, from a public health perspective, this has been a highly successful strategy for building the country's disease-immune population base.[54] The National Conference on State Legislatures has noted, "[t]he

48. Fiore, *supra* note 35, at 711.

49. Paul Bolton et al., *Deficiencies in Current Childhood Immunization Indicators*, PUB. HEALTH REP. (Nov., 1998), http://www.findarticles.com/p/articles/mi_m0835/is_6_113/ ai_53459067 (last visited Feb. 20, 2005).

50. WORLD HEALTH ORGANIZATION (WHO), GLOBAL ALLIANCE FOR VACCINES AND IMMUNIZATION (GAVI) (Fact Sheet No. 169, March 2001), http://www.who.int/mediacentre/factsheets/fs169/en/ (last visited Feb. 20, 2005) [hereinafter GAVI].

51. COMMUNICABLE DISEASE SURVEILLANCE AND RESPONSE (CSR), WHO, 2001 - MENINGOCOCCAL DISEASE IN THE AFRICAN MENINGITIS BELT – UPDATE 5 (Apr. 5, 2001), *at* http://www.who.int/csr/don/2001_04_05/en/ (last visited Feb. 20, 2005).

52. 197 U.S. 11 (1905) (holding that a Massachusetts statute requiring adults to be vaccinated does not violate the Fourteenth Amendment).

53. *See* James G. Hodge, *School Vaccination Requirements: Legal and Social Perspectives*, 27 NATIONAL CONFERENCE OF STATE LEGISLATURES (NCSL) STATE LEGISLATIVE REPORT (August 2002), http://www.ncsl.org/programs/health/schoolvaccination.pdf (last visited Feb. 24, 2005) (discussing compulsory school entry vaccination programs). Pre- and continuing (monitoring) employment vaccination and health guidelines exist at the federal level for Hepatitis B. Individual states must be at least as stringent, and may exceed federal guidelines, regarding vaccines that should be offered and for which workers may be at risk, depending upon the job, worksite, and exposure risk (such as annual influenza vaccine for health care workers). Guidance for Hepatitis B can be found at OCCUPATION SAFETY AND HEALTH ADMINISTRATION (OSHA), U.S. DEP'T OF LABOR, SCREENING AND SURVEILLANCE: A GUIDE TO OSHA STANDARDS, OSHA 3162 (2000), http://www.osha.gov/Publications/osha3162.pdf (last visited Feb. 24, 2005).

54. Hodge, *supra* note 53, at 2, 7.

rate of fully vaccinated school-age children in the United States (greater than 95 percent) is as high, or higher, than most other developed countries."[55] To protect Americans from the introduction of vaccine-preventable diseases from nonindigenous populations, the United States Department of State requires immigrants to obtain certain vaccinations (such as Mumps, Measles, Rubella, Polio, Pertussis, Influenzae Type B, Hepatitis B, Varicella, Pneumococcal, Influenza, and Tetanus/Diptheria Toxins) prior to the issuance of an immigrant visa.[56]

II. SMALLPOX – OLD SCOURGE

Smallpox has afflicted humanity for thousands of years, causing epidemics from ancient times through the twentieth century. Human remains and written records retell the global devastation of smallpox from early civilizations, including fourth century China, seventh century India, and tenth century Asia.[57] Tradesmen and invading tribes were effective vectors of disease introduction to susceptible populations.[58] The Egyptian practice of mummification preserved the skin, musculature, and bones of a large number of royal personages, and diagnoses of the causes of death of several mummified persons have been made by paleopathologists; the scientific literature mentions three mummies, including Ramses V, whose skin was covered with lesions that looked like those of a smallpox rash.[59] Over the next several centuries:

> Smallpox reached Europe (between the 5th and 7th centuries) and was present in major European cities by the 18th century. Epidemics occurred in the North American colonies in the 17th and 18th centuries. At one time smallpox was a significant disease in every country throughout the world except Australia and a few isolated islands.[60]

---

55. *Id.* at 7.

56. BUREAU OF CONSULAR AFFAIRS , U.S. DEP'T. OF STATE , NEW VACCINATION REQUIREMENTS FOR IV APPLICANTS: IMPORTANT NOTICE TO IMMIGRANT VISA APPLICANTS CONCERNING VACCINATION REQUIREMENTS (2004), *at* http://travel.state.gov/visa/immigrants_info_vaccinations.html (last visited Feb. 24, 2005).

57. FRANK FENNER ET AL., WHO, THE HISTORY OF SMALLPOX AND ITS SPREAD AROUND THE WORLD IN SMALLPOX AND ITS ERADICATION 210 (1988).

58. *Id.*

59. CURRENT SCIENCE & TECHNOLOGY CENTER, BOSTON MUSEUM OF SCIENCE, SMALLPOX: AN ANCIENT DISEASE (2004), *at* http://www.mos.org/cst/article/5109/2.html (last visited Feb. 24, 2005). Nicolau Barquet & Pere Domingo, *Smallpox: The Triumph Over the Most Terrible of the Ministers of Death*, 127 ANNALS OF INTERNAL MED. 635 (1997), http://www.annals.org/cgi/content/full/127/8_Part_1/635 (last visited Feb. 24, 2005).

60. FENNER ET AL., *supra* note 57.

According to the WHO, "the disease, for which no effective treatment was ever developed, killed as many as 30% of those infected."[61] Furthermore, "[b]etween 65–80% of survivors were marked with deep pitted scars (pockmarks), most prominent on the face."[62] Smallpox was responsible for a third of all reported cases of blindness in eighteenth century Europe, killing "every 10th child born in Sweden and France."[63] Similarly, "during the same century, every 7th child born in Russia died from smallpox."[64] As demonstrated by an 1898 survey conducted in Vietnam, 95% of children were pockmarked and nine-tenths of all blindness was attributed to smallpox.[65] Smallpox continued to persist worldwide into the nineteenth and twentieth centuries as well, until the vaccine was developed.[66]

The continued devastation of populations from smallpox led the WHO to set aside a malaria eradication campaign in favor of a smallpox eradication program. The WHO initiated this effort under the name "Intensified Smallpox Eradication Programme" in 1967.[67] Success was heralded when the last case was reported in 1977, and the disease was officially declared eradicated by the WHO by 1980.[68] The eventual elimination of naturally occurring smallpox is considered a remarkable victory over human disease.[69]

III. SMALLPOX – NEW THREAT?

One of the greatest United States foreign policy challenges and global security perils is the threat of biological weapons, including smallpox, and other weapons of mass destruction that may be harbored and capable of deployment by hostile nations and terrorist states. Such weapons would cause large-scale (mass) destruction of life and dislocation of civil order and economic structures.

The end of the Cold War and the dissolution of the former Soviet Union and its offensive bioweapons (BW) program resulted in the dispersal of large quantities

61. WHO, SMALLPOX (WHO FactSheet, 2004), *at* http://www.who.int/mediacentre/factsheets/smallpox/en/ (last visited Feb. 24, 2005).

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. David A. Koplow, *That Wonderful Year: Smallpox, Genetic Engineering, and Bio-Terrorism*, 62 MD. L. REV. 417, 433 (2003).

68. *Id.* at 436.

69. WHO, SMALLPOX ERADICATION – A GLOBAL FIRST (1998), *at* http://www.who.int/archives/who50/en/smallpox.htm (last visited Feb. 24, 2005).

of weapons, materials, and scientists.[70] There is reason to believe that these resources may have made their way into the hands of rogue nations and non-state actors.[71] There is also information suggesting that the smallpox virus is accessible outside the restricted environments of the two depositary sites, the Russian State Research Center of Virology and Biotechnology (Vector) near Novosibirsk, and the Centers for Disease Control and Prevention (CDC) in Atlanta.[72]

International treaties do exist that prohibit the development, production, stockpiling, acquisition, and use of biological weapons.[73] Although these programs, which have been in place for years, may prevent participating nations from the offensive use of smallpox, they will not prevent terrorists or rogue nations, who are not bound to abide by these accords.[74] Similarly, these terrorists are unlikely to fear retaliation for deploying weaponized smallpox.

The CDC has categorized potential agents according to level of threat using specific criteria including: public health impact, such as transmissibility and ability to cause illness and death; ease of production; ability to cause grotesque or frightening symptoms; requirement of special preparations to "weaponize" or disseminate the agent; and, deliverability by aerosol or via contamination of food or water.[75] On this basis, the CDC has classified potential bioterrorism threat agents into three categories designated A, B, or C.[76] Of the three, Category A

---

70. Wolfgang F. Klietmann & Kathryn L. Ruoff, *Bioterrorism: Implications for the Clinical Microbiologist*, 14 CLIN. MICROBIOLOGY REVS. 364, 367 (Apr. 2001), http://cmr.asm.org/cgi/content/full/14/2/364 (last visited Feb. 24, 2005).

71. *See id.*

72. *See id.* at 367, 376. *See also* Press Release, The White House, President Delivers Remarks on Smallpox, (Dec. 13, 2002), http://www.whitehouse.gov/news/releases/2002/12/20021213-7.html; Barton Gellman, *Four Nations Thought to Possess Smallpox: Iraq, N. Korea Named, Two Officials Say*, WASH. POST, Nov. 5, 2002, at A1, *available at* 2002 WL 102569475.

73. *E.g.*, Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, Apr. 10, 1972, 26.1 U.S.T. 583, 1015 U.N.T.S. 163 [Hereinafter Biological Weapons Convention]; Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, June 17, 1925, 26 U.S.T. 571, 94 L.N.T.S. 65. Signatories include many countries of concern to the United States, such as Iraq, Iran, and North Korea. Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, 2002; Holly Myers et al., *The Threat of Smallpox: Eradicated but not Erased*, J. HOMELAND SECURITY (Feb. 2004), *at* http://www.homelandsecurity.org/journal/Articles/gursky_smallpox.html (last visited Feb. 24, 2005).

74. *See* Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction (Nov. 10-14, 2003), http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp17.pdf (last visited Feb. 24, 2005).

75. CDC, BIOTERRORISM AGENTS/DISEASES, CATEGORY DEFINITIONS (2003), *at* http://www.bt.cdc.gov/agent/agentlist-category.asp#catdef (last visited Feb. 24, 2005).

76. *Id.*

agents are the highest-priority agents that pose a risk to national security because they:

- can be easily disseminated or transmitted from person to person;
- result in high mortality rates and have the potential for major public health impact;
- might cause public panic and social disruption; and
- require special action for public health preparedness.[77]

Smallpox, as well as Botulism, Plague, Tularemia, and Viral hemorrhagic fevers, are considered Class A agents.[78] The CDC has categorized smallpox as a Class A agent because it is a high-priority agent that poses a risk to national security for the reasons listed above.[79]

IV. THE PHASE I CIVILIAN SMALLPOX VACCINATION PROGRAM

The 2002 decision to vaccinate civilians against smallpox represented the extraordinary intersection of human susceptibilities and deliberate biological threats. Routine smallpox vaccination was discontinued in 1972 in the wake of the successful WHO smallpox eradication program,[80] and individuals vaccinated prior to that time are believed to have limited residual immunity.[81] Therefore, the fact that over one-third of Americans are fully susceptible[82] renders the variola or smallpox virus an excellent biological weapon.[83] With the omnipresent memory of the recent terrorist acts against the United States reflecting *intent,* information suggesting the presence of weapons of mass destruction indicating c*apability*, and the recognition of a *vulnerable* United States population,[84] concerns about the

77. *Id.*

78. *Id.*

79. *Id.*

80. JONATHAN B. TUCKER, SCOURGE: THE ONCE AND FUTURE THREAT OF SMALLPOX 138 (2001).

81. Erika Hammarlund et al., *Duration of Antiviral Immunity After Smallpox Vaccination,* 9 NATURE MED. 1131 (2003); William J. Bicknell, *The Case for Voluntary Smallpox Vaccination*, 346 NEW ENG. J. MED. 1323 (2002).

82. Dr. James J. James, Director, Miami-Dade Co. Health Dep't, Letter to the Editor, AM. MED. NEWS, Jan. 14, 2002, http://www.ama-assn.org/amednews/2002/01/14/edlt0114.htm (last visited Feb. 24, 2005).

83. For more information on smallpox characteristics, see AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ), DHHS, THE CURRENT THREAT OF SMALLPOX BIOLOGICAL WEAPONS (Oct. 15, 2001), *at* http://www.bioterrorism.uab.edu/CategoryA/Smallpox/current.html (last visited Feb. 24, 2005).

84. *See* Veronique de Rugy & Charles V. Peña, *Responding to the Threat of Smallpox Bioterrorism: An Ounce of Prevention is Best Approach,* POL'Y ANALYSIS NO. 434 (Apr. 18, 2002), http://www.cato.org/pubs/pas/pa434.pdf (last visited Feb. 24, 2005) (describing the threat assessment

potential dire consequences of a deliberate smallpox release were justifiably elevated among high level decision-makers and public health and medical experts in the post-9/11 climate.

The premise of the Phase I civilian smallpox vaccination program was the creation of a phalanx of vaccinated medical, public health, and other emergency responders who could be sent into smallpox epicenters to vaccinate susceptible individuals, separate the ill from the non-ill exposed persons, and apply medical and epidemiological expertise to contain the outbreak.[85] Based on estimates suggesting a requirement of 100 vaccinated and specialized healthcare workers per hospital, the Advisory Committee on Immunization Practices recommended that "smallpox response teams" comprised of 510,000 healthcare workers from across America's 5100 acute care hospitals be vaccinated nationally.[86]

Initially proposed to be followed by Phase II and Phase III, ultimately providing both a wider responder group and non-responder civilians access to the smallpox vaccine, the Phase I plan to vaccinate "smallpox response teams"[87] gained traction as America moved closer to war with Iraq. In fact, Phase I was promoted as a component of general bioterrorism preparedness efforts and not necessarily tied to a particular threat.[88]

The Phase I civilian smallpox vaccination program encountered a number of problems, some predictable and others that, in retrospect, were not afforded sufficient thought and collaborative planning to adequately support this large-scale initiative. Individually and collectively these problems contributed to the nation's inability to achieve its Phase I vaccination goals.

A. Legal Protections – The Right to Bare Arms

The vaccine is made from a virus called *vaccinia,* a "pox"-type virus related to smallpox.[89] The smallpox vaccine contains the "live" vaccinia virus, and can have side effects leading to such complications as redness and soreness near the

---

model used by Col. Lani Kass (USAF, Ret.) at the National War College: "Vulnerability x Intentions x Capabilities = Threat").

85. *See* Press Release, The White House, Protecting Americans: Smallpox Vaccination Program (Dec. 13, 2002), http://www.whitehouse.gov/news/releases/2002/12/print/20021213-1.html (last visited Feb. 24, 2005) [hereinafter Protecting Americans].

86. Robert Roos, *ACIP Suggests Which Hospital Workers Need Smallpox Shots; Total Could Reach 500,000*, CIDRAP NEWS (Ctr. for Infectious Disease Research & Pol'y (CIDRAP)), Oct. 18, 2002, http://www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/aciprecs.html (last visited Feb. 24, 2005).

87. Protecting Americans, *supra* note 85.

88. *See The Smallpox Vaccination Plan: Challenges and Next Steps: Oversight Hearing Before the Senate Comm. on Health, Education, Labor and Pensions*, 108th Cong. (Jan. 30, 2003) (testimony of Dr. Julie L. Gerberding, Director, CDC), http://help.senate.gov/testimony/001_tes.html (last visited Feb. 24, 2005) [hereinafter Gerberding, *The Smallpox Vaccination Plan*].

89. *Id.*

vaccination site, enlargement and soreness of glands in the armpits, low-grade fever, and difficulty sleeping; one out of three people may feel ill enough to miss work and/or school.[90] According to the CDC, "in the past, about 1,000 people for every 1 million people vaccinated for the first time experienced reactions that, while not life-threatening, were serious [and] may [have] require[d] medical attention."[91]

The vaccinia vaccine carries with it a range of side effects, from "mild," including fever, generalized body ache, and fatigue (1,000 of every 1 million vaccinated), to "serious" or potentially life-threatening effects such as progressive vaccinia and postvaccinal encephalitis (14-52 of every 1 million vaccinated), to "fatal" (life-threatening reactions that occur in one to two people out of every 1 million vaccinated).[92] Vaccinia is contraindicated in individuals who have any immune-suppressing condition; eczema, atopic or other exfoliative dermatologic conditions; women who are pregnant or breastfeeding; and children under one year of age.[93] Furthermore, because vaccinia is a live virus which "sheds" from the vaccination site until scab separation up to three weeks later, these contraindications hold not only for individuals who are vaccinated but also for their household and other close contacts.[94]

These risks placed formidable constraints on the cohort of potential vaccinees, especially those who constituted the direct health care provider pool. Concerns were exacerbated by today's demographics, which are vastly different from the 1970's when routine smallpox vaccination was discontinued.[95] It is estimated that the numbers of immune-compromised people – and their contacts – include individuals with Human Immunodeficiency Virus (HIV), cancers, and post-organ transplant use of immunosuppressive drugs, which may constitute over 25% of the United States population.[96] Both health care workers and their

90. CDC, DHHS, SMALLPOX FACT SHEET: REACTIONS AFTER SMALLPOX VACCINATION (March 28, 2003), http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/reactions-vacc-public.pdf (last visited Feb. 24, 2005) [hereinafter REACTIONS AFTER SMALLPOX VACCINATION].

91. *Id.* For a detailed report of the rate of complications, see CDC, DHHS, VACCINIA (SMALLPOX) VACCINE: RECOMMENDATIONS OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP), 2001, 50 MMWR: RECOMMENDATIONS AND REPORTS 1, 8 tbl. 3 (June 22, 2001), http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf [hereinafter MMWR RECOMMENDATIONS].

92. REACTIONS AFTER SMALLPOX VACCINATION, *supra* note 90; MMWR RECOMMENDATIONS, *supra* note 91.

93. *See* MMWR RECOMMENDATIONS, *supra* note 91, at 11.

94. CDC, SMALLPOX FACT SHEET: WHAT TO DO AFTER YOU'VE GOTTEN THE SMALLPOX VACCINE (Jan. 14, 2003), http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/site-care-pub.pdf (last visited Feb. 24, 2005).

95. CDC, DHHS, CLINICAL EVALUATION TOOLS FOR SMALLPOX VACCINE ADVERSE REACTIONS (2004), *at* http://www.bt.cdc.gov/agent/smallpox/vaccination/clineval/ (last visited Feb. 24, 2005).

96. CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, U.S. FOOD AND DRUG ADMIN., HEALTHY PEOPLE 2000: NATIONAL HEALTH PROMOTION AND DISEASE PREVENTION OBJECTIVES: 5.

employers – the hospitals – recognized the risks at which they were placing their personnel and patients by endorsing their participation in the Phase I program.

Unlike previous "pre-event" mass vaccination programs, the Phase I civilian smallpox program was afforded a relatively limited set of legal protections. Congress enacted Section 304 of the Homeland Security Act in November 2002.[97] Section 304 extended liability coverage to those engaged in administering vaccines,[98] but left vulnerable others involved in the chain of providing medical countermeasures, such as those responsible for screening civilians recruited for vaccination as a contingency of their assignment to a "smallpox response team."[99] Absent a no-fault compensation system, the federal government erroneously assumed that other programs, such as state workers' compensation, would provide the necessary legal remedy. In fact, this assumption was not a remedy universally accepted across the country.[100] Furthermore, Section 304 held no provisions for compensating the families or patients of vaccinees who might be inadvertently and adversely affected.[101] HHS Secretary Tommy G. Thompson's attempts to broaden Section 304's liability protections on January 28, 2003, did little to alleviate concerns.[102]

Further attempts at legislative relief came on April 30, 2003, after Congress enacted the Smallpox Emergency Protection Personnel Act of 2003 (SEPPA),[103] which created a no-fault compensation regime. However, among its many flaws, SEPPA was secondary to other sources of compensation, like workers' compensation, and created more ambiguity and concern than it relieved. Furthermore, SEPPA's limited caps on awards, compensation for lost employment, and survivor benefits did little to reinvigorate a languishing Phase I program. Even before the first vaccination on January 24, 2003,[104] hospitals, professional organizations, and labor unions, although supportive of the program's *premise*, voiced concerns regarding a *process* that failed to provide adequate legal

---

BARRIERS AND CHALLENGES (Sept. 1995), http://vm.cfsan.fda.gov/~mow/hp2kbar.html (last visited Feb. 24, 2005).

97. Homeland Security Act of 2002, Pub. L. No. 107-296, § 304, 116 Stat. 2135, 2165 (codified at 6 U.S.C.S. § 184 (Law. Co-op. 2002)).

98. *Id.*

99. *Id.*

100. Myers et al., *supra* note 73.

101. *Id.*

102. *Id.*

103. Smallpox Emergency Personnel Protection Act of 2003 (SEPPA), Pub. L. No. 108-20, 117 Stat. 638 (codified in scattered sections of 42 U.S.C.S. (Law. Co-op. 2003)). Smallpox Compensation Program, 42 C.F.R. pt. 102.

104. Pamela Ferdinand & Ceci Connolly, *Turnout Low at Launch of Domestic War on Smallpox; Conn. First State to Carry Out Bush's Immunization Campaign*, WASH. POST, Jan. 25, 2003, at A12, *available at* 2003 WL 10892751.

protections to the institutions and professionals at greatest risk. This is evidenced by the following statements:

> America's hospitals and health systems support this voluntary vaccination program . . . [but believe] that the government may view this provision [that hospitals that are not actually administering smallpox vaccinations on-site would not be protected from liability] too narrowly . . . .[105]

> The [American Academy of Pediatrics] recommend[s] the ring strategy rather than universal or voluntary immunization, [because] potentially serious health risks from the vaccine weighed against the possibility, currently thought to be unlikely, that a smallpox attack could occur.[106]

> The [American Nurses Association] is . . . concerned about whether the current risk outweighs the burden, both human and financial, that such a large vaccination program will place on already strained health care provider resources . . . .[107]

> The President's plan to inoculate as many as 500,000 health care workers nationwide for smallpox fails to adequately protect these workers, their families and their patients.[108]

> [T]he American Public Health Association [urges opposition to the Smallpox Emergency Personnel Protection Act] in its current form . . . and strongly supports legislation to address current impediments to the national smallpox preparedness effort, including lack of compensation for those who become injured, ill, disabled or die; protections from liability for volunteer vaccinators and health systems; and adequate

---

105. American Hospital Association (AHA), Hospitals' Views on the Federal Smallpox Vaccine Program, Statement before the Institute of Medicine Committee on Smallpox Vaccination Program Implementation (Dec. 19, 2002), *at* http://66.77.118.213/aha/advocacy-grassroots/advocacy/testimony/test021219smallpox.html (last visited Feb. 24, 2005).

106. Press Release, American Academy of Pediatrics (AAP), AAP Supports 'Ring Vaccination' in Case of Smallpox Outbreak (Oct. 7, 2002), http://www.aap.org/advocacy/ archives/octsmallpox.htm (last visited Feb. 24, 2005).

107. American Nurses Association (ANA), Statement before the Institute of Medicine's Committee on Smallpox Vaccination Program Implementation (Dec. 19, 2002), http://nursingworld.org/news/disaster/dec17cmts.pdf (last visited Feb. 24, 2005).

108. Statement by John J. Sweeney, AFL-CIO President, Need for Better Safeguards to Protect Health Care Workers Targeted for Smallpox Vaccine (Dec. 13, 2002), *at* http://www.aflcio.org/media center/prsptm/pr12132002a.cfm (last visited Feb. 24, 2005).

> federal resources to enable public health systems to implement a smallpox vaccination program safely and effectively.[109]

The fact that a relatively *low value* of legal protections was afforded to persons recruited to receive what was perceived to be a relatively *high-risk* vaccine was, perhaps, the most serious flaw in the Phase I civilian smallpox program. In fact, a 2004 study of the Phase I program revealed that "the lack of an adequate smallpox vaccine liability and compensation scheme was one of the largest obstacles to the United States' achieving its goal of vaccinating 500,000 first responders."[110]

B. Systems and Systemic Failures

In the event of a case of smallpox, a critical mass of well-trained, rapidly deployed, and vaccinated medical and public health personnel would be required to identify, track, and vaccinate persons at risk in order to avert high levels of infection and death. Swift and robust actions are required to identify and vaccinate a "ring" of exposed individuals around an infected case to reduce epidemic disease spread.

Disease transmission was a concern beyond issues associated with averting high levels of morbidity and mortality. At the inception of the Phase I program, the country was in possession of relatively "old" but viable vaccine stock, however sufficient in undiluted form to provide only 15.4 million doses.[111] To assure a dose for all 293 million Americans,[112] the country engaged in an accelerated program of vaccine production that was announced by Secretary Thompson on March 28, 2002.[113]

The smallpox vaccine, vaccinia, despite its notable side effects, can prevent disease – or reduce its severity – only if administered within three to four days

---

109. Letter from Dr. Georges Benjamin, Executive Director, American Public Health Association (APHA), to the House of Representatives (Mar. 30, 2003), http://www.apha.org/legislative/legislative/letters/smallpox_rep20030330.htm (last visited Feb. 24, 2005).

110. Myers et al., *supra* note 73.

111. Robert Roos, *Trial of Aventis Smallpox Vaccine Getting Under Way,* CIDRAP NEWS (Ctr. For Infectious Disease Research & Pol'y), June 28, 2002, http://www.cidrap.umn.edu/cidrap/content/bt/smallpox/news/avent.html (last visited Feb. 24, 2005).

112. Randy Dotinga, *Wanted: Drugs to Fight Bioterror,* WIRED NEWS, June 2, 2004, *at* http://www.wired.com/news/medtech/0,1286,63655,00.html (last visited Feb. 24, 2005); *see also* Ceci Connolly, *Aventis to Donate Smallpox Vaccine; With Sudden Increase in Supply, U.S. Is Reevaluating Inoculation Policy,* WASH. POST, Mar. 30, 2002, at A02, *available at* 2002 WL 17586662 (last visited Feb. 24, 2005).

113. Press Release, DHHS, NIAID Study Results Support Diluting Smallpox Vaccine Stockpile to Stretch Supply (Mar. 28, 2002), http://www.hhs.gov/news/press/2002pres/20020328b.html (last visited Feb. 24, 2005).

after exposure to the virus.[114] There was reason to question the nation's ability to successfully accomplish this time-sensitive task. Over the past several decades the public health "system," a confederation of approximately 2,800 local and fifty state public health departments, has been underfinanced and overtaxed by a myriad of non-infectious disease responsibilities, including the delivery of a wide array of medical services.[115] The overall numbers of personnel constituting the public health workforce and its rapid disease containing and mass vaccinating capabilities have been successively depleted.[116] The hospital sector has also been adversely affected by an array of cost-cutting efforts and regulatory measures that have reduced bed capacity and nursing, technology and support personnel.[117]

The scale, continuity, and integration of efforts required to identify, isolate, and vaccinate persons at risk, provide palliative care for individuals infected with a disease which has no cure, and track and monitor ongoing disease incidence necessitated the integration of efforts between the public health and medical sectors. Owing, in part, to the current and historical disconnects between the public health and medical sectors, some hospitals felt they were not involved sufficiently early in the process of planning the Phase I event, and could not inform and facilitate the process.[118] Furthermore, smallpox vaccination was not a skill set at ready access to the physicians and nurses who would not only potentially serve as vaccinees, but who would also carry the burden of vaccinating other responders.[119] Unlike the typical intramuscular immunization administered with a needle and syringe, smallpox vaccination requires fifteen "jabs" (perpendicular insertions on the deltoid area of the upper arm) with an unfamiliar tool – the bifurcated needle.[120]

Potential vaccinators had a steep learning curve that included practical skills – the technique of vaccinating – as well as understanding the vaccine and its contraindications, administering appropriate history taking and screening to avoid vaccinating individuals for whom vaccinia was medically contraindicated, and advising vaccinees on appropriate post-vaccination site care to prevent auto-

114. Donald A. Henderson et al., *Smallpox as a Biological Weapon*, 281 JAMA 2127, 2132 (June 9, 1999).

115. *See* ELIN GURSKY, THE CENTURY FOUNDATION, PROGRESS AND PERIL: BIOTERRORISM PREPAREDNESS DOLLARS AND PUBLIC HEALTH, A CENTURY FOUNDATION REPORT 5-6, 15 (2003), http://www.tcf.org/Publications/HomelandSecurity/Gursky_Progress_Peril.pdf (last visited Feb. 24, 2005).

116. *Id.* at 15.

117. *See id.*

118. *See* Myers et al., *supra* note 73.

119. *See id.*

120. Jennifer M. Lofquist et al., *Smallpox: A Review of Clinical Disease and Vaccination*, 60 AM. J. HEALTH-SYS. PHARMACY 749, 752 (Apr. 29, 2003).

inoculation[121] or inadvertently vaccinating others. Because routine smallpox vaccinations had been discontinued over 30 years ago, the disease and its preventive efforts were unfamiliar to most currently practicing clinicians.[122] Until recently, smallpox was something relegated to the medical history books.

Individually, the hospital and public health sectors faced a unique preventive medicine challenge. Collectively this was rendered more difficult because of insufficient numbers of prior opportunities to integrate objectives and workforce. The disconnect between these two sectors was more glaring within the high visibility, high stakes context of the Phase I Smallpox Vaccination program.

C. Funding the Phase I Plan - Show Us The Money

Since fiscal year 1999, state and local health departments have received relatively modest amounts of funding for bioterrorism preparedness through the CDC's Bioterrorism Preparedness and Response Program.[123] In January 2002, HHS announced the availability of $918 million in supplemental funding to improve general preparedness.[124] Application for this funding was due by April 15, 2002, with plans proposing to follow the CDC cooperative guidance document that targeted achieving improved capabilities in six areas: planning and readiness assessment; surveillance and epidemiology capacity; laboratory capacity; communications and information technology; risk communications and health information; and education and training.[125]

This was the largest one-time funding ever made available to the public health sector and represented the seriousness of the government's intentions to assure the protection of the domestic population against new biosecurity threats. For the public health sector this represented an adjusted business case that required thoughtful consideration of their operating systems, including: encumbering and dispersing sizable funds; revising tables of organization; purchasing relatively "big ticket" items like computers and other communication and information equipment; and training large numbers of personnel about novel biological agents, like anthrax and smallpox.[126] There were many obstacles to vault that affected legislative, financial, and political processes at the state and local levels.[127]

---

121. Inadvertently transferring virus from the vaccine site to another part of the body is referred to as "auto-inoculation." MILLER-KEANE'S ENCYCLOPEDIA & DICTIONARY OF MEDICINE, NURSING, & ALLIED HEALTH 155 (5th ed. 1992).

122. Gerberding, *The Smallpox Vaccination Plan, supra* note 88.

123. U.S. GENERAL ACCOUNTING OFFICE (GAO), SMALLPOX VACCINATION: IMPLEMENTATION OF NATIONAL PROGRAM FACES CHALLENGES 10 (2003), http://www.gao.gov/new.items/d03578.pdf (last visited Feb. 24, 2005) [hereinafter GAO].

124. *Id.*

125. *Id.*

126. *See* GURSKY, *supra* note 115, at 5-6, 34.

127. *See id.* at 46.

The CDC Cooperative Guidance for the Bioterrorism Preparedness and Response Program did not specifically address smallpox. When the public health sector was informed, rather precipitously, that it needed to redirect its preparedness efforts to a specific smallpox initiative, they had "less than 3 weeks to develop their plans and less than two months to prepare to begin vaccination."[128] Preparations included developing and submitting "pre-attack" vaccination plans to the CDC that covered the size of each Smallpox Response Team; the location of each vaccination site; the number of health care facilities identified to participate in the Phase I program; information on vaccine logistics and security, training, and data management; and other key aspects of their plans.[129] Public health was in its usual position of doing more than it was funded to do with very little notice, but in the unusual position of attempting to do it under the lens of the nation. Furthermore, the sudden and rather onerous amount of work and the plans on which their deliverables would be based was placed before the public health sector without benefit of smallpox program-specific funding.

There were preliminary calculations regarding the Phase I smallpox plan that estimated the basic cost of administering the vaccine at $13 per vaccinee.[130] The Association of State and Territorial Health Officials (ASTHO) and the National Association of City and County Health Officials (NACCHO) estimated the per vaccinee costs at $265 and $204, respectively, and stressed that the CDC had significantly underestimated the full costs involved through the entirety of the planning to the post-vaccination follow-up process, which NACCHO claimed could be as high as $1,784 per vaccinee.[131] Furthermore, the CDC made no new funds available for the Phase I program, anticipating that states could redirect a portion of the preparedness funds released some six months earlier.[132] States claimed that these funds had already been encumbered for their initial bioterrorism preparedness and response planning activities.[133] State public health departments did not have "spare" money to underwrite the Phase I program, which many viewed as an unfunded mandate, especially during a fiscal crisis projecting that states would face fiscal year 2004 budget deficits of between $70 billion and $85 billion.[134] Hospitals were also underfinanced to assume the costs involving staff

128. GAO, *supra* note 123, at 4.

129. *Id.* at 8; Gerberding, *The Smallpox Vaccination Plan*, *supra* note 88.

130. GAO, *supra* note 123, at 17.

131. *Id.*

132. *See id.*

133. *Id.*

134. IRIS J. LAV & NICHOLAS JOHNSON, CENTER ON BUDGET AND POLICY PRIORITIES, STATE BUDGET DEFICITS FOR FISCAL YEAR 2004 ARE HUGE AND GROWING (Jan. 23, 2003), http://www.cbpp.org/12-23-02sfp.pdf (last visited Feb. 24, 2005).

time, materials, supplies (such as bandages), treatment, and sick leave as a result of vaccination-related adverse events.[135]

It was not just the direct costs associated with holding meetings, creating planning documents, traveling to potential vaccination sites, and acquiring and storing vaccine and two-pronged needles, as well as an array of other expenses, that took its toll on the Phase I program. The "indirect" costs, though more difficult to calculate, were nonetheless of high importance to the public health officials who saw the smallpox efforts diverting attention and efforts from their routine, mandated, and essential public health services.[136] More importantly, many public health practitioners believed the smallpox efforts subverted their primary preparedness and response activities and the previously planned vision of building a more generalized capabilities architecture (not just something "smallpox" specific) to address a potentially wide spectrum of biological hazards, other mass casualty events, and natural disasters.[137] The public health sector worked hard to accomplish their smallpox vaccination goal, but many saw little results from their efforts. One study reports comments made by several participants that the Smallpox Plan "stopped us dead in the water;" "[c]urtailed virtually all other BT work;" "[t]otally derailed planning efforts for many months;" and "[i]t took everything we had for months – and no one was vaccinated."[138]

D. Adversely Affected – Reactions to the Smallpox Vaccine

Adverse reactions to the smallpox vaccine are usually mild, but may also persist to the point of requiring treatment in certain individuals. Past experience indicates that between fourteen and fifty-two people per 1 million vaccinated for the first time experienced potentially life-threatening reactions.[139] The rates of adverse reactions may be lower for persons who have been previously vaccinated.[140]

Adverse event rates in the United States today may be higher because there may be more people at risk from immune suppression (from cancer, cancer therapy, organ transplants, and illnesses such as HIV/AIDS) and eczema or atopic dermatitis.[141] However, the outcomes associated with adverse events may be less severe than previously reported because of advances in medical care.

---

135. GAO, *supra* note 123, at 18.

136. *See id* at 18.

137. *See id.*

138. GURSKY, *supra* note 115, at 36.

139. CDC, DHHS, SMALLPOX FACT SHEET: VACCINE OVERVIEW (2004), http://www.bt.cdc.gov/agent/smallpox/vaccination/pdf/vaccine-overview.pdf (last visited Feb. 24, 2005) [hereinafter VACCINE OVERVIEW].

140. *Id.;* REACTIONS AFTER SMALLPOX VACCINATION, *supra* note 90.

141. *See* VACCINE OVERVIEW, *supra* note 139.

Studies from 1968 assessing complications from smallpox vaccinations given in the United States show that out of the estimated 5.6 million vaccinations that were given, adverse reactions included postvaccinial encephalitis, progressive vaccinia, eczema vaccinatum, generalized vaccinia, accidental infection, and other complications.[142] There is a lack of good historical data regarding the adverse sequelae following smallpox vaccination in *adults* because, prior to the discontinuation of regular vaccinations, the smallpox vaccine was routinely administered to *children* as part of their neonatal and infant immunization schedule.[143]

As a result of the Phase I program, adverse reactions included general vaccinia (n=3), inadvertent inoculation (n=21), myocarditis/pericarditis (n=21), ocular vaccinia (n=3), postvaccinial encephalitis (n=1), other serious adverse events (n=100), and other nonserious adverse events (n=745).[144] Investigation determined a likely causal relationship between smallpox vaccination and myopericarditis (an inflammation of both the heart muscle and its covering); the relationship between heart pain (angina) and heart attack following smallpox vaccination remains under investigation.[145] Nevertheless, reports of adverse reactions – although not unexpected – were a deterrent.[146] Upon hearing of cardiac-related events, a number of states discontinued their Phase I programs.[147] Other states implemented more rigorous screening of potential vaccination candidates and excluded persons who might previously have qualified for vaccination.[148] These actions contributed to reducing the pool from which to recruit smallpox vaccinees.[149]

E. Operation Iraqi Freedom – The Toils of War

The spirit of patriotism and service to mankind that has driven people to roll bandages in earlier periods of war, or donate blood during times of disaster, was evidenced in the initial stages of the Phase I Smallpox Vaccination Program.

---

142. Henderson et al., *supra* note 114, at 2134-35.

143. *See id.* at 2129.

144. CDC OFFICE OF COMM., DHHS, ADVERSE EVENTS ASSOCIATED WITH SMALLPOX VACCINATION AMONG CIVILIANS (2004), *at* http://www.cdc.gov/od/oc/media/spcivil.htm (last visited Feb. 24, 2005). *See also* CDC, DHHS, UPDATE: ADVERSE EVENTS FOLLOWING CIVILIAN SMALLPOX VACCINATION – UNITED STATES, 2003, 53 MMWR 106 (Feb. 13, 2004) [hereinafter ADVERSE EVENTS FOLLOWING CIVILIAN SMALLPOX VACCINATION], http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5305a4.htm (last visited Feb. 24, 2005).

145. CDC, DHHS, *Update: Cardiac-Related Events During Civilian Smallpox Vaccination Program - United States, 2003*, 290 JAMA 31, 34 (July 2, 2003).

146. Myers et al., *supra* note 73.

147. *Id.*

148. *Id.*

149. *Id.*.

During the commencing weeks of Operation Iraqi Freedom, states experienced a relative surge in volunteers seeking to become vaccinated volunteers.[150] Moreover, the recent memories of attacks on the homeland, both from planes and envelopes, loomed in the minds of a vulnerable America. There were reports of disgruntled individuals who demanded access to vaccination, even though they did not qualify for – or wish to participate in – the Smallpox Response Teams.

Many states noted that they did not capitalize on the war to "market" vaccination and participation in the Phase I Program, but most agreed that a waning perception of threat resulted in waning participation.[151] The failure to find weapons of mass destruction in the Iraqi theater resulted in a significant lack of enthusiasm for participating in the civilian vaccination program.[152]

F. Where There's a (Political) Will, There's a Way

The Phase I Smallpox Vaccination Program began with a galvanized spirit of protecting the nation from a possible threat perceived to be in the hands of "regimes hostile to the United States."[153] While acknowledging that there was no information that a smallpox attack was imminent, President Bush announced on December 13, 2002:

> We do recommend vaccinations for one other [nonmilitary] group of Americans that could be on the front lines of a biological attack. We will make the vaccine available on a voluntary basis to medical professionals and emergency personnel and response teams that would be the first on the scene in a smallpox emergency.[154]

Ten months later, the director of the CDC was reported to have said, "the United States never launched a smallpox vaccination program this year, but instead worked toward an overall preparedness campaign."[155] One year after the start of the Phase I initiative, HHS Secretary Thompson announced that "the 'vast majority' of states are now prepared to immunize all their residents in 10 days if there were [sic] a smallpox bioterrorism attack."[156] This statement was

---

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.*

154. Press Release, The White House, President Delivers Remarks on Smallpox, (Dec. 13, 2002), http://www.whitehouse.gov/news/releases/2002/12/20021213-7.html (last visited Feb. 24, 2005).

155. David McGlinchey, *CDC Director Denies Existence of Smallpox Immunization Program*, GLOBAL SECURITY NEWSWIRE, Nov. 18, 2003, *at* http://www.nti.org/d_newswire/issues/2003_11_18.html#4154B89C (last visited Feb. 24, 2005).

156. David McGlinchey, *HHS Secretary says 'vast majority' of states ready for smallpox*, GOV'T EXECUTIVE, Jan. 29, 2004, http://www.govexec.com/dailyfed/0104/012904d2.htm (last visited Feb. 24, 2005).

subsequently challenged by Representative Jim Turner (D-TX), ranking member of the House Select Committee on Homeland Security.[157]

The rhetoric was confusing at best and underscored the sometimes contentious climate in which sectors across the nation were scrambling to deter, detect, and mitigate threats to the homeland security. Many tried, but it may be that some tried harder.

In May 2003, four months after the first vaccination, the *New York Times* ran an article with the following statement:

> The pattern is not uniform, but it is strong. Of the 15 states with the highest vaccination rates, Bush carried all but one, Minnesota. The states Bush carried by the biggest margins tend to have the highest rates; the ones that Gore won overwhelmingly have among the lowest.[158]

In a study of twenty states calculating the ratio of persons vaccinated to the number of anticipated vaccination volunteers (extrapolated from vaccine doses shipped to states by the CDC), "high yield" and "low yield" states were compared on a number of factors.[159] "High yield" states tended to assume that compensation issues would be addressed by worker's compensation, "borrowed" money from state general funds to cover the costs of an initiative not specifically federally funded at the outset, encouraged meetings with hospitals, produced and distributed through a variety of modes educational and motivational materials for potential volunteers, and engaged in an array of other, more "assertive" efforts than their colleagues in "low yield" states.[160] Eight of the ten "high yield" states had Republican governors, while eight of the ten "low yield" states had Democratic governors.[161]

V. CONCLUSION

The Phase I Smallpox Vaccination Program is all but over. Many states have long-discontinued their vaccination efforts and some have moved residual smallpox vaccination program funds into budget lines where, many believe, monies can be put to more relevant and immediate use. Approximately 40,000

157. David McGlinchey, *HHS Secretary asked to back up smallpox claim*, GOV'T EXECUTIVE, Apr. 6, 2004, http://www.govexec.com/dailyfed/0404/040604d2.htm (last visited Feb. 24, 2005) (noting that Rep. Turner claimed "top Bush administration officials were not doing enough to protect the nation from a smallpox terrorist attack").

158. Richard Perez-Pena, *Voting for Bush, Voting to Get a Smallpox Shot*, N.Y. TIMES, May 18, 2003, § 4, at 2.

159. Myers et al., *supra* note 73.

160. *See id.*

161. *Id.*

Americans have received a vaccine that will protect them from a threat this country may never have to face.[162] They and over 600,000 vaccinated troops should be recognized for their support of this country's efforts to protect the nation's security in the event of a smallpox attack.[163]

One can view the Phase I Program through an "after action" approach that tallies the wins, the losses, and the lessons learned. Foremost among the "wins" was the opportunity for the public health and hospital sectors to engage in discussion and problem solving. Requirements to rapidly detect, prevent, and contain diseases will require interdependence between the disease experts who deal with patients (medicine) and the disease experts who deal with populations (public health), as well as other critical sectors. In a future that portends *potential* acts of terrorism and the *certainty* of large-scale epidemics and outbreaks of naturally occurring diseases, the smallpox experience has demonstrated the importance of professional unity, consensus, and close operational relationships.

Among the most regrettable "losses" was a loss of trust, a phenomenon that occurred across multiple levels. Hospitals, clinicians, professional organizations, labor unions, and potential vaccinees expected that their sacrifices of time and the potential risk to self and others would be met with appropriate levels of legal protections. In fact, whether driven by budgetary restrictions or a perceived urgency of effort that impeded sufficient consideration of the scope of the issue, inadequate regimes of liability and compensation eroded – early on – attempts to vaccinate anywhere near the intended number of 500,000 civilian emergency responders.

Moreover, there was a huge lack of congruence between *input*, the time and efforts expended, and *outcome*, the eventual number of people vaccinated. Time was spent on training vaccinators who did not vaccinate, in holding clinics to which few came, and to reconstituting vaccines that went unused and wasted. These precious resources of human capital and budget may have been better used towards other preparedness efforts more critical to protecting the nation.

It is hoped that the lessons learned from the Phase I Smallpox Vaccination Program will be applied to ongoing preparedness efforts. The country is at war and the future holds many uncertainties. Smallpox, and other biological weapons, pose true threats to America that demand an array of well-considered strategies and countermeasures.

---

162. ADVERSE EVENTS FOLLOWING CIVILIAN SMALLPOX VACCINATION, *supra* note 144.

163. Mark K. Arness et al., *Myopericarditis Following Smallpox Vaccination*, 160 AMER. J. EPIDEMIOLOGY 642 (2004).