WHO Knows Best? National and International Responses to Pandemic Threats and the “Lessons” of 1976

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ABSTRACT: The discovery of a novel influenza strain at Fort Dix, New Jersey, in 1976—dubbed Swine Flu—prompted differing responses from national and international health organizations. The United States crafted a vaccination campaign to inoculate every citizen; conversely, the World Health Organization (WHO) recommended a ‘wait and see’ policy. An examination of the WHO conference that issued the influenza policy reveals the decision was driven by the limits of its member states’ ability to produce inactivated vaccine and concern over the premature use of unstable live-virus vaccines. The WHO recommendation’s reliance upon an uneven surveillance system would have replicated the 1957 and 1968 vaccination failures if a pandemic had appeared. **KEYWORDS:** Swine Flu, influenza, influenza vaccines, pandemic planning, World Health Organization (WHO).

IN late winter/early spring, technicians at a public health laboratory initiated a series of typing tests on a suspected influenza sample. The laboratory was one link in a chain of laboratories that comprised the global influenza surveillance system, and the assay was one of many thousands conducted during influenza season. The initial results were unusual, but not completely unexpected. The experiments had confirmed that the virus was influenza, but its specific identification was unknown, a situation that occasionally happens with these typing efforts. Very quickly,

JOURNAL OF THE HISTORY OF MEDICINE AND ALLIED SCIENCES, Volume 65, Number 4

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Advance Access publication on March 15, 2010

doi:10.1093/jhmas/jrqq002

however, other samples of this as-yet-unidentified-strain were uncovered and epidemiological research rapidly determined that the virus was associated with an increasing number of cases. A novel virus with sustained person-to-person spread suggested that a pandemic was a distinct possibility. In response to the new influenza virus, dubbed "Swine Flu" by the media, World Health Organization (WHO) officials hurriedly called for an emergency meeting of influenza experts in Geneva. The assembled experts were tasked with evaluating the new influenza situation and with crafting recommended courses of actions for the Director-General to use in advising WHO member states. If the experts concluded that the new strain would prompt a pandemic, the only viable protective option for national health programs was to produce inactivated influenza vaccines on a crash emergency basis. On 7–8 April, influenza researchers from more than a dozen nations gathered in Geneva to evaluate the epidemiological evidence and draft a recommendation for the Director-General. Drawing upon the scientific evidence of the virus, its spread, and the capabilities of national health programs, the experts reported their conclusions. With this influenza expert assessment in hand, the Director-General counseled member states on the best courses of action to pursue in light of the new virus. Although the above events sound like they are drawn from today's headlines, this crisis year of a possible influenza pandemic was 1976, not 2009.

In 1976, the discovery of a novel influenza strain causing a chain of infections prompted a dramatic public health response by the United States. The United States opted to mount an emergency vaccination campaign officially titled the "National Influenza Immunization Program" but commonly called the Swine Flu Program, and this large-scale vaccination effort has been amply documented.¹ The Swine Flu Program was marred by a series of logistical problems ranging from the production of the wrong

1. See, for example, Richard E. Neustadt and Harvey V. Fineberg, *The Swine Flu Affair: Decision Making on a Slippery Disease* (Washington, DC: U.S. Department of Health, Education, and Welfare, 1978); Arthur Silverstein, *Pure Politics and Impure Science* (Baltimore and London: Johns Hopkins University Press, 1981); Sharon L. Begley, "Failure of the 1976 Swine Flu Drive," *Yale J. Biol. Med.*, 1977, 50, 645–57; and Walter R. Dowdle, "The 1976 Experience," *J. Infect. Dis.*, 1997, 176, Suppl. 1, S69–S72.

vaccine strain to a confrontation over liability protection to a temporal connection of the vaccine and a cluster of deaths among an elderly population in Pittsburgh. The most damning charge against the vaccination program was that the shots were correlated with an increase in the number of patients diagnosed with an obscure neurological disease known as Guillain–Barré syndrome. The program was halted when the statistical increase was detected, but ultimately the *New York Times* labeled the program a “fiasco” because the feared pandemic never appeared.² It is this label of “fiasco” that has lingered in the public mind.

Retrospective examinations of the events in 1976 have been generally critical of the U.S. program with the decision-making process coming under especially harsh scrutiny.³ The events at Fort Dix heralded a problem of global concern. However, these investigations of a national program to combat a global disease have focused solely on the United States. This exclusive focus on the United States is somewhat surprising as international health organizations, most notably the WHO, had long played a role in tracking and preparing for pandemic influenza. Often overlooked in the examination of the Swine Flu Program is the fact that the WHO had called an emergency meeting of influenza experts to prepare a recommendation for the Director-General to help him advise member states on the best public health options to pursue. Many nations relied upon the WHO to help them develop a public health response.

Crafting public health policy is a mixture of science and politics. What causes a disease, what factors are associated with its spread, and how one can protect the public are scientific questions. So also are the processes of identifying the potential threat, evaluating a range of responses, and offering a recommended course of action. Whether the costs of protection are justified by the threat, who should pay for this protection, and if the steps necessary for protection are acceptable to society are political questions. Ultimately, deciding which, if any, response to pursue and what level of cost is

2. Harry Schwartz, “Swine Flu Fiasco,” *New York Times*, 21 December 1976, A33.

3. Neustadt and Fineberg’s *The Swine Flu Affair* is the most influential investigation of the program. Silverstein’s *Pure Politics and Impure Science* seeks to refute some aspects of Neustadt and Fineberg’s criticism.

too high is also a political decision. In the WHO, this mixture of science and politics is further complicated by the uneven range of health-care infrastructures among the member states. Simply put, the options may be beyond the means of many members, complicating the range of recommendations the WHO can make.⁴

Accordingly, the WHO faces difficult challenges in spearheading international public health. One of the functions of the WHO is to “stimulate and advance work to eradicate epidemic, endemic, and other diseases.”⁵ The WHO also defines “health” broadly. Health is a “state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity.”⁶ However, to achieve these lofty aims, the WHO has few independent resources beyond assemblies of experts and scientific working groups and is therefore heavily reliant upon national health organizations to carry out WHO recommendations. Implementing WHO guidelines relies on persuading—or pushing—national health organizations to adopt WHO suggestions. Although this description of the relationship between the WHO and national health organizations remains broadly accurate, influenza recommendations are somewhat of an exception to this pattern of relations.

Influenza pandemics were readily recognized as threats to global public health by the WHO, and from its very founding the WHO has steadily increased its role in coordinating research laboratories that identify and track new influenza strains. From modest beginnings in a few borrowed rooms at Mill Hill in the UK, today the network of laboratories spans 128 national influenza centers located in ninety-nine countries and includes five WHO collaborating centers for influenza research.⁷ The “cornerstone” for WHO work

4. Here I model this discussion from Walter Dowdle who argues that risk assessment is a scientific process, while risk management is a political process. Although difficult in practice, Dowdle suggests that there is value in separating the process of scientific recommendations from political discussions. Dowdle, “The 1976 Experience,” S69–S72.

5. From the “Constitution of the World Health Organization,” article 2 (g). From the World Health Organization web site, <http://www.who.int/en/> (accessed 11 October 2007).

6. From the “Constitution of the World Health Organization,” from the World Health Organization web site, <http://www.who.int/en/> (accessed 11 October 2007).

7. Founding of the World Influenza Centre from M. M. Kaplan, “The Role of the World Health Organization in the Study of Influenza,” *Philos. Trans. R. Soc., London. Ser. B*, 1980, 288, 417–21, 417–18, and current figures from: <http://www.who.int/csr/disease/influenza/influenzanetwork/en/index.html> (accessed 25 October 2009).

on influenza, however, has been its “annual recommendations on influenza vaccine formulation and related activities.”⁸ Twice a year, the WHO gathers a panel of experts—drawn from the Influenza Collaborating Centers, national health programs and from the WHO—who decide which strains of influenza should be included in the forthcoming influenza vaccine. Upon this consultation, the WHO issues its recommendations and ships the seed viruses to manufacturers for production. Only rarely have national health organizations attempted to modify the WHO-recommended vaccine composition. Because of the more active role the WHO plays in the field of influenza, WHO recommendations on influenza carry more weight than its other pronouncements on health.

In 1976, the United States Public Health Service (USPHS) decided that the events at Fort Dix merited a dramatic public health response. Initially, the WHO matched its evaluation of the potential dangers from this new viral strain with the United States. However, as the USPHS increasingly came to favor a massive vaccination campaign, the WHO began to distance itself from the U.S. recommendation, eventually counseling a far more cautious response. This article traces the evolution of the WHO experts’ recommendation from the initial discovery of the Swine Flu virus at Fort Dix through the 7–8 April 1976 WHO experts’ meeting that drafted the WHO recommended response. What factors shaped the WHO’s interpretation of the virus’ pandemic potential? What “lessons” can be drawn from the WHO decision?

WHO AND INFLUENZA

The WHO’s longtime role in influenza surveillance and its involvement in distributing vaccine candidate strains gave it a prominent voice in influenza matters. WHO surveillance programs took on an especially important responsibility when a new influenza strain was detected. In the pandemic years of 1957 and 1968, the WHO had spearheaded the task of charting the spreading pandemic and in assisting national health programs in their efforts to mount protective vaccination programs. Despite the WHO’s efforts, these national vaccination efforts were ineffectual. The pandemics peaked before any nation could distribute and inject sufficient vaccine

8. K. Stohr, “The WHO Global Influenza Program and Its Animal Influenza Network,” *Avian Dis.*, 2003, 47, 934–38, 935.

doses to protect their populations. This vaccination program failure was the result of a combination of a fast moving virus, slow vaccine production methods, and delayed distribution programs.

Following the failed vaccine effort of 1968, international influenza experts had been meeting at conferences sponsored by the National Institutes of Health to pool research on the influenza virus and to discuss preventative strategies.⁹ The plan to successfully combat a pandemic relied on two key points: increased global surveillance to catch a new viral strain as early as possible and an enhanced manufacturing process using new technologies to produce faster growing/higher yielding influenza hybrids.¹⁰ However, influenza experts, in 1976, recognized that there were serious problems with both surveillance and manufacturing. An international meeting of influenza experts was convened at Rougemont, Switzerland, in January 1976, to discuss—among other things—just these issues of surveillance and manufacturing.¹¹ The major problem with surveillance was that significant gaps in coverage existed, particularly in so-called developing nations. Although Walter Dowdle (Director of the Virology Division of the CDC, which was also one of two—the UK was the other—Coordinating Centers for WHO Influenza Surveillance in 1976) pointed out that WHO support had improved surveillance in developed nations, he expressed concern about “the poor or non-existent surveillance in the developing areas of

9. These meetings were subsequently published in *J. Infect. Dis.* See “Influenza Virus Polypeptides and Antigens—Summary of Influenza Workshop I,” *J. Infect. Dis.*, 1972, 125, 447–56; “Immunologic Methodology in Influenza Diagnosis and Research—Summary of Influenza Workshop II,” *J. Infect. Dis.*, 1972, 126, 219–30; “Specific Immunity in Influenza—Summary of Influenza Workshop III,” *J. Infect. Dis.*, 1973, 127, 220–36; “Epidemiology of Influenza—Summary of Influenza Workshop IV,” *J. Infect. Dis.*, 1973, 128, 361–86; “Influenza Vaccines—Summary of Influenza Workshop V,” *J. Infect. Dis.*, 1974, 129, 750–71; “Animal Influenza: Its Significance in Human Infection—Summary of Influenza Workshop VI,” *J. Infect. Dis.*, 1975, 131, 602–12; “Genetics, Replication, and Inhibition of Replication of Influenza Viruses—Summary of Influenza Workshop VII,” *J. Infect. Dis.*, 1975, 132, 713–23; and “Antiviral Agents in Influenza—Summary of Influenza Workshop VIII,” *J. Infect. Dis.*, 1976, 134, 516–27.

10. This technology, pioneered by Edwin Kilbourne, wedded the new viral type with a fast-growing laboratory strain. Technically a reassortment of the two viruses, the fastest growing, highest yielding strain that produced effective preventative immunity to the new virus was selected for vaccine production. See Edwin Kilbourne, “Future Influenza Vaccines and the Use of Genetic Recombinants,” *Bull. WHO*, 1969, 41, 643–45 and Harold M. Schmeck Jr., “Race for a Swine Flu Vaccine Began in a Manhattan Lab,” *New York Times*, 21 May 1976, B1.

11. Philip Selby, ed., *Influenza: Virus, Vaccines, and Strategy, Proceedings of a Working Group on Pandemic Influenza, Rougemont, January 1976* (London: Academic Press, 1976).

the world.”¹² There would be no hope of manufacturing a protective vaccine in sufficient time to protect the public unless surveillance was able to quickly identify an emerging pandemic.

The value of large-scale vaccination campaigns was clearly recognized by influenza researchers in the early 1970s. As J. W. G. Smith stated at the Rougemont Conference, the “wide use of vaccination, in the general population as well as in high-risk groups, is likely to be worthwhile in attempting to limit the impact of pandemic influenza as much as possible,” and while admittedly expensive, attempting to control a pandemic would produce “benefits [that] might outweigh the costs of such a program.”¹³ Although several nations possessed the technical capabilities to produce a protective inactivated vaccine, they lacked the facilities to do so, but according to Smith, “presumably . . . developed countries could, by increasing their production facilities, produce sufficient vaccine to immunize their entire populations.”¹⁴ In 1976, the only protection against pandemic influenza was vaccination. When the novel strain of influenza was detected at Fort Dix, New Jersey, the United States immediately alerted the WHO and vaccine manufacturers. If a vaccination campaign was deemed necessary, all involved in the process of producing vaccines would have to move fast.

FORT DIX AND THE WHO

The discovery of a new strain of influenza at Fort Dix was, in many ways, an anticipated event. In addition to the fact that international and national health organizations had been furiously preparing for just such a new viral discovery, the strain at Fort Dix (in technical terms an H15N1 influenza A strain) fit two predictive theories that posited that a novel influenza strain should spark a pandemic around the year 1978, and that it should be related to the 1918

12. Summary of discussion, Chairman W. R. Dowdle, *rapporteur*, accompanying J. W. G. Smith, “Surveillance and Early Warning,” in *Influenza: Virus, Vaccines, and Strategy*, ed. Selby, 89–92, 91. The general discussion followed the eight papers that comprised the first session, “Surveillance and Early Warning,” and presumably included all twenty-eight meeting participants. See *Influenza: Virus, Vaccines, and Strategy*, ed. Selby, 23–92.

13. J. W. G. Smith, “Vaccination Strategy,” in *Influenza: Virus, Vaccines, and Strategy*, ed. Selby, 271–94, 271 and 291.

14. *Ibid.*, 279.

Spanish Flu, also an H1N1.¹⁵ The identification of the new strain at Fort Dix, called A/New Jersey in honor of its original discovery, set off an intensive investigation. The U.S. Army medical investigators took the lead in determining the number of cases at Fort Dix. The Army estimated that about five hundred soldiers had been infected, clearly demonstrating human transmission. Army influenza expert Colonel F. H. Top, Jr. reported that positive reactions to tests for swine influenza were clustered in platoons that had identifiable Swine Flu infections (one platoon had 63 percent positive tests, and others ranged between 30 and 50 percent) and that these positive reactions were only found in the cohorts that had begun training in January and early February. This epidemiological information was quickly reported to the WHO.¹⁶

The WHO worked closely with the Center for Disease Control (CDC) in the days following the identification of the new virus and initially copied the lead of the U.S. organization in evaluating the potential pandemic danger of the new strain. In fact, the WHO went beyond exchanging information and coordinated research

15. The eleven-year-cycle held that a new virus sparked a pandemic about every eleven years. The last pandemic influenza year was 1968. The recycling theory held that a limited number of viral types infected the human population and that as the population aged, those with immunity to a strain type formed a lesser percentage of the population making the conditions ripe for a reemergence of a viral type. See Edwin Kilbourne, "Epidemiology of Influenza," in *Influenza Viruses and Influenza*, ed. Edwin Kilbourne (New York: Academic Press, 1975), 483–538 and "Specific Immunity in Influenza—Summary of Influenza Workshop III," *J. Infect. Dis.*, 1973, 127, 220–23, see especially chart on 221 for a comprehensive description of the eleven-year-cycle theory. The recycling theory and how it was understood following the 1968 Hong Kong Flu is drawn from Fred M. Davenport, "Prospects for the Control of Influenza," *Am. J. Nurs.*, 1969, 69, 1908–11 and F. M. Davenport, E. Minuse, A. V. Hennessy, and T. Francis, Jr., "Interpretations of Influenza Antibody Patterns of Man," *Bull. WHO*, 1969, 41, 453–60. The eleven-year-cycle theory has been abandoned and the recycling theory has come under sharp criticism. See W. R. Dowdle, "Influenza A Virus Recycling Revisited," *Bull. WHO*, 1999, 77, 820–28. Dowdle argues that the evidence does not substantiate the predictive pattern of influenza recycling.

16. See chart in "Influenza-A/Swine Serologic Survey-Fort Dix, 17–27 Feb. 76," Box 21, folder titled "Swine Flu-Ft. Dix, etc.," RG 442, National Archives and Records Administration, South East Region (hereafter cited as NARA's SE Region). The military survey information was reported to the CDC on 1 March 1976 and Walter Dowdle informed Charles Cockburn, WHO Director, Division of Communicable Diseases, on 2 March 1976. See Dowdle's handwritten notebook titled "Ft. Dix Log Book, Feb. '76," Box 32, RG 442, NARA's SE Region. Top reported the five hundred infection estimate at the influenza workshop held 25 March 1976. See transcript from "Center for Disease Control, Bureau of Biologics, National Institute of Allergy and Infectious Disease Influenza Workshop March 25, 1976," 15, Box 32, unlabeled folder T-1 (2), RG 442, NARA's SE Region.

with the CDC to avoid duplication.¹⁷ The WHO also sent three influenza experts as observers (Paul Bres, Geoffrey Schild, and John Skehel) to the crucial 10 March 1976 Advisory Committee on Immunization Practices (ACIP) meeting where the evidence of Fort Dix was presented and possible responses—including a massive vaccination campaign—were debated.¹⁸ WHO observer Bres even commented that it was probably “safest to go [with] the vac” during the discussion of what response the USPHS should adopt.¹⁹ Bres and Schild penned a report on the ACIP meeting for the WHO where they commented that “man-to-man transmission of the virus was amply demonstrated,” and that “one interpretation of the man-to-man transmission of a virus which has not been prevalent in the population for 65 years indicated the emergence of a pandemic situation.”²⁰ In their report, Bres and Schild described in great detail the various vaccination plans discussed by the ACIP, including the plan to inoculate the entire population of the United States. The WHO observers were sufficiently impressed by the discussion that in their personal comments attached to the end of the report they suggested that “a meeting might be convened with the producers of vaccines in Europe at a date pending the deliberation of the Bureau of Biologics which will be known soon.”²¹ This meeting was designed to discuss creating a similar vaccination campaign among nations that could mount a crash program of vaccine production.

17. See G. C. Schild, Vaccine Studies in the U.K. [underlined in original], Box 32, unlabeled folder, loose papers, RG 442, NARA's SE Region. It is unclear when Schild presented this list of experiments to Walter Dowdle, but it was likely to have been when Schild came to the United States for the 10 March 1976 Advisory Committee on Immunization Practices meeting.

18. For a discussion of the meeting, see Neustadt and Fineberg, *Swine Flu Affair*, 10–16 and George Dehner, “Comparing National and International Responses to the Threat of Pandemic Disease: Examining National and International Responses to the ‘Swine Flu’ of 1976” (PhD diss., Northeastern University, December 2004), 109–15.

19. WHO observer Paul Bres from J. Lyle Conrad's handwritten notes from the 10 March ACIP meeting, Box 37, file titled “Files ACIP Flu Meeting–March 1976,” RG 442, NARA's SE Region.

20. “Report for the Meeting of the Advisory Committee on Immunization Practices, Center for Disease Control, Atlanta, Georgia, U.S.A., 10 March 1976, Prepared by Dr. P. Bres, Chief Medical Officer, Virus Diseases, WHO, Geneva, and Dr. G. Schild, N. I. B. S. C., London,” Box 32, unlabeled folder T-1 (3), RG 442, NARA's SE Region.

21. Ibid. The Bureau of Biologics was the branch of the USPHS that was concerned with purity and potency of vaccines. In 1972, the bureau was moved to the Food and Drug Administration from the National Institutes of Health.

From the initial identification of the new virus at Fort Dix through the 10 March 1976 ACIP meeting, the WHO and the USPHS had an identical vision of the pandemic threat posed by the novel strain. The assessment of the potential danger caused by viruses prompted U.S. health officials to consider a massive vaccination campaign to protect its citizens, and momentum for that decision began to build rapidly following the 10 March meeting. During this same time period, however, WHO officials began to develop a different, milder depiction of the future course of the new virus and to seek an alternative to a large-scale vaccination effort. Such a revised assessment increasingly put WHO officials at odds with USPHS officials.

THE PRESIDENT ANNOUNCES

On 24 March 1976, U.S. President Gerald Ford held a high-profile emergency meeting with a select group of scientific advisors about the proper response to the new virus. The meeting was followed by a press conference announcing the plan to inoculate every “man, woman, and child in the United States.”²² The president’s call for a massive vaccination program drew prominent media coverage. However, in addition to the president’s announcement, the broadcast and print media widely reported the response of an unnamed WHO official who stated that the WHO was “surprised by the American plan for vaccine,” and that “no other countries have plans for mass inoculations.”²³ This very public “surprised” comment was a blow to the validity of the U.S. decision in the eyes of the public as officials had repeatedly emphasized that the WHO and health organizations from other nations had coordinated closely in investigating the Fort Dix outbreak.²⁴ Embarrassed U.S. officials would either have to explain why the WHO was unaware of their plans or why no other

22. President Ford, “The President’s Remarks Announcing Actions to Combat the Influenza,” *Weekly Compilation of Presidential Documents*, 24 March 1976, 12, 483–84.

23. See “To: H. F. [Harvey Fineberg] and R. E. N. [Richard E. Neustadt] from T. K. [?], Re: Evening News Coverage of Swine Flu as Abstracted in Vanderbilt Television News Archive Index and Abstracts (March 25, 1976),” Box 44, file titled “Press Briefing 10/12/76–1977,” RG 442, NARA’s SE Region for television coverage and Harold M. Schmeck Jr., “Test of Flu Vaccine Expected in April,” *New York Times*, 26 March 1976, A14, for print coverage.

24. See, for example, “H. Bruce Dull’s Press Conference Influenza—Thursday February 19, 1976” announcing the Swine Flu strain discovery, Box 44, binder titled “Flu 1,” tab “Feb. 19 Press Conference,” RG 442, NARA’s SE Region.

nations were planning a vaccination campaign. Therefore the United States reacted quickly and strongly to the WHO official's comments.

U.S. officials immediately pressured the WHO to publicly endorse their decision. One unnamed ACIP Advisor stated that "We had to beat the hell out of them" in order to get the WHO to vouch for the program.²⁵ As the largest donor to the United Nations and the WHO, the United States had a powerful voice in these organizations.²⁶ The pressure worked: by the next day WHO officials were quoted in the news media as stating "WHO endorses President Ford's plan for massive inoculation against swine flu virus."²⁷ U.S. officials explained away the initial WHO comment as coming from someone who was not fully informed of the evidence bolstering the decision. Once fully informed, the WHO officially backed the decision.²⁸ The endorsement from the WHO, however, merely papered over the emerging differences between the USPHS and the WHO as to the correct response to the Fort Dix discovery. This split over the proper course of action would continue to widen over the ensuing weeks and would eventually prove to be impossible to hide.

Although U.S. health officials tried to brush aside the first WHO criticism of the U.S. vaccination decision, it soon became apparent that the WHO was reluctant to copy the U.S. recommendation of

25. Anonymous ACIP advisor from Lawrence Wright, "Sweating out the Swine Flu Scare," *New Times*, 11 June 1976, 28–38, 38. Wright's article was considered an accurate account of behind the scenes activity at the CDC.

26. The United States contributed almost forty million dollars in fiscal year 1977, which was over 25 percent of the entire WHO budget. United Nations, *Yearbook of the United Nations, 1976, Volume 30* (New York: Office of Public Information, United Nations, 1979), 975.

27. See "Memo To: H. F. [Harvey Fineberg] and R. E. N. [Richard E. Neustadt] from T. K. [?], Re: Evening News Coverage of Swine Flu as Abstracted in Vanderbilt Television News Archive Index and Abstracts (March 27, 1976)," Box 44, file titled "Press Briefing 10/12/76–1977," RG 442, NARA's SE Region.

28. See, for example, Theodore Cooper's (Assistant Secretary for Health, HEW) testimony to the Senate Subcommittee of the Committee on Appropriations, *Preventative Health Services and Employment Programs Emergency Supplemental Appropriations*, Hearing on H. J. Res. 890, 94th Cong., 2nd Sess., testimony of Theodore Cooper, 6 April 1976, 30. Sir John Skehel, one of the three representatives for WHO, at the March 10 ACIP meeting suggests that the support comment came from Paul Bres and that the "surprised" comment came from Fakhry Assaad. Assaad was part of the Division of Virology at WHO headquarters in Geneva, but unlike Bres was not directly involved in the Swine Flu investigation. There are a surprisingly small number of WHO expert staff at Geneva and they are pulled in many different directions because the WHO has to respond to emergencies of all sorts. Sir John Skehel, personal interview, 6 September 2007.

a large-scale inoculation program. Even in the 26 March 1976 WHO press release issued in support of the U.S. vaccination decision, the WHO began to draft a rationale for not recommending a massive inoculation program for other national health programs. The press release characterized the evidence generated from Fort Dix much more benignly than U.S. officials had, stating that “the new strain satisfies some of the criteria associated with pandemic strains” but “it is impossible at this time to predict whether it will spread since from previous experience it is known that some strains spread rapidly and others do not.”²⁹ The statement emphasized that “the cases due to the new strain at the camp were no more severe than those due to the current strain which was in the camp at the same time.”³⁰ This moderate depiction of A/New Jersey’s pandemic potential stood in sharp contrast with pronouncements from the USPHS which stated that “If major changes occur in the virus . . . vast epidemics or ‘pandemics’ are expected” and “present evidence and past experience indicate a strong possibility that this country could experience widespread swine influenza in 1976–77.”³¹

The conscious or unconscious desire to find evidence that A/New Jersey might not be a global threat explains the “no more severe” label of A/New Jersey in the WHO press release. By emphasizing that A/New Jersey was similar to the prevailing strain, the authors of the release hoped to ease fears of the unspoken

29. “Press Release WHO/16, 26 March 1976, Close Watch on New Flu Strain [underlined in original],” on file at the World Health Organization Library and Information Networks for Knowledge, Geneva. Press releases are unsigned but are designed to represent the view of the Director of the Division associated with the topic and ultimately he or she is responsible for it even if not directly the author. Occasionally, a press release is issued that causes some embarrassment for the Division Chief. See, for example, A. M. M. Payne’s (Section of Endemo-Epidemic Diseases, Division of Communicable Disease Services) letter to Dr. Dorland Davis (National Microbiological Unit, National Institutes of Health) dated 11 February 1953, apologizing for an over-optimistic press release. Since this was the only case I encountered of a WHO official apologizing for an official press release in WHO correspondence on influenza between the years 1949 and 1977, I have concluded that press releases, in general, accurately reflect the opinion of the WHO Division Director. Letter from Payne to Davis, 11 February 1953, World Health Organization Archives, WHO 2, DCINFL, 6 R.I.C. 3, (microfiche) Geneva, Switzerland (hereafter WHO Archives).

30. Press Release WHO/16, 26 March 1976, Close Watch on New Flu Strain [underlined in original].

31. J. Donald Millar’s Draft—23 March 1976, “OPS Objective on Influenza,” Box 32, unlabeled folder “T-1 (2),” and “March 24, 1976, The White House Fact Sheet Swine Influenza Immunization Program,” Box 44, binder “Flu-1,” tab “March 14–20,” RG 442, NARA’s SE Region.

question surrounding the new virus: was this Swine Flu a new visitation of the Spanish Flu which had killed at least 20 million people?³² The evidence suggested that A/New Jersey and Spanish Flu were antigenically related, meaning that those who had experienced the 1918 flu produced some protective antibodies when exposed to A/New Jersey. But whether A/New Jersey was as virulent as the Spanish Flu was unknown and as yet unknowable.

The clearest indication that the WHO was not going to follow the lead of the United States was visible in the press release statement that "Assuming the new strain could trigger off large epidemics, this is the first occasion in which such a strain has been isolated early enough for vaccines to be mass-produced ahead of time. Widespread rapid vaccination *in the country where the strain has first appeared* could greatly reduce the risk for the rest of the world."³³ Here the WHO was ascribing a motive to the U.S. decision that USPHS officials never claimed; they never expressed their purpose as being to protect "the rest of the world." The USPHS was planning to inoculate all citizens from Hawaii to Maine, and make the vaccine available to all U.S. citizens around the globe. Indeed, how to get the doses to various regions of the globe was a topic of debate within the State Department, who had rejected using the diplomatic pouch.³⁴ A program of injections beginning in September offered no chance of halting spread from New Jersey. USPHS officials seriously doubted they had uncovered the original mutation (or shift) of the virus and feared that swine influenza could be arising anywhere around the globe, a point USPHS

32. The relationship to Spanish Flu played no official role in the decision by the USPHS and most influenza scientists rejected the notion that A/New Jersey was neo-Spanish Flu. It is undeniable that the Spanish Flu connection greatly facilitated passage and funding of the USPHS's vaccination plan. See Neustadt and Fineberg, *Swine Flu Affair*. Updated estimates on Spanish Flu's toll suggest that the global mortality was about fifty million. However, the authors acknowledge that this total may underestimated by up to 100 percent, meaning the total could be as high as one hundred million. Niall P. A. S. Johnson and Juergen Mueller, "Updating the Accounts: Global Mortality of the 1918–1920 'Spanish' Influenza Pandemic," *Bull. Hist. Med.*, 2002, 76, 105–15, 115.

33. Emphasis mine. Press Release WHO/16, 26 March 1976, Close Watch on New Flu Strain [underlined in original].

34. See "Memorandum for Honorable Spencer Johnson, Subject: Swine Flu Immunization of Non-Official Americans Overseas, from W. Delano Meriwether (Special Assistant to Assistant Secretary for Health; Director, National Influenza Immunization Program, Health, Education, and Welfare)," from Box 32, unlabeled folder, T-1 (4), RG 442, NARA's SE Region.

officials were still making several months later. "Is surveill [ance] any better now? No. Brush fires always occur. It's possible we've stumbled on the first—but not likely" (underlined in original).³⁵ The WHO's characterization of the intent of the U.S. vaccination plan was at best faulty and at worst disingenuous.

The cautious attitude that the WHO was beginning to develop is somewhat surprising. International experts agreed that the influenza virus was no mean threat. CDC and WHO laboratory director Walter Dowdle estimated that in the period between 1957 and 1977, influenza had been responsible for "two pandemics, 12 epidemics, over 400,000 excess deaths, untold billions in medical costs, and countless hours lost from work or school" in the United States alone.³⁶ The WHO had been actively involved in the pandemic years of 1957 and 1968 by tracking the emerging pandemic, distributing vaccine seed stock and reagents to nations around the world, and facilitating the distribution of information about the virus to help accelerate national vaccination campaigns. In the wake of the failed 1968 vaccination effort around the globe, health officials determined that rapid decision-making and an accelerated manufacturing process offered the only hope of producing sufficient doses of vaccine to protect the public from an influenza pandemic, at least for the foreseeable future. Indeed, influenza experts from various national health programs that had just met in January at Rougemont, Switzerland, concluded that the mere identification of a new viral subtype provided "sufficient evidence on which to initiate a global alert."³⁷

The evidence of serial transmission of a novel virus at Fort Dix, combined with the high-profile U.S. vaccination campaign, mandated that the WHO influenza experts meet to advise the WHO Director-General as to what recommended courses of action, if any,

35. J. Lyle Conrad's handwritten notes from the 5/26 Conference of State and Territorial Health Epidemiologists meeting dated "5/26," from Box 37, file titled "ACIP Flu Meeting March 1976," RG 442, NARA's SE Region.

36. Walter R. Dowdle and J. Donald Millar, "Swine Influenza: Lessons Learned," *Symposium on Infectious Disease, Med. Clin. of North Am.*, 1978, 62:5, 1048. This material was collected from papers stored at the Centers for Disease Control, internally labeled "Box 4 of 6," accession number 442-00-0058.

37. Summary of discussion, Chairman W. R. Dowdle, *rapporteur*, accompanying J. W. G. Smith, "Surveillance and Early Warning," in *Influenza: Virus, Vaccines, and Strategy*, ed. Selby, 89–92, 89.

member states should pursue. Accordingly, a special meeting of influenza experts was called for 7–8 April 1976 in Geneva. The meeting was designed to evaluate the potential threat of the new strain and prepare a list of recommendations to report to the Director-General of the WHO. It is important to note that such recommendations are not binding and are not the official policy of the WHO.³⁸ As we have seen, however, the expert recommendations in the field of influenza research carry special weight as the twice-yearly vaccine recipes came in the form of expert recommendations.

Thus far, influenza experts associated with the WHO had refrained from openly criticizing the U.S. vaccination decision, at least by name. However, on the eve of the special meeting in Geneva, this policy began to change. The first overt challenge to the U.S. program came from a surprising—and to USPHS officials, a dismaying—source. Geoffrey Schild, Chief of the United Kingdom's National Institute for Biological Standards and Control in London was recently the head of the World Influenza Centre laboratory in the UK and remained a very prominent influenza expert. On the eve of the April 1976 Geneva meeting, Schild—who as we have seen was an official observer for the WHO at influenza meetings in the United States—was quoted as characterizing the U.S. influenza program as a “‘somewhat immoderate response’ to the Ft. Dix flu phenomenon.”³⁹ Intentional or not, Schild's critique suggested that the U.S. decision was either unscientific, hasty, or a combination of the two. This characterization of the program implied that the decision to undertake a massive vaccination campaign was based on factors beyond influenza science. Domestic critics in the United States charged that the program was a political plan to bolster the president during an election year and criticism of the U.S. decision carried over into the Geneva conclave.⁴⁰

38. A point sometimes not clear to members of expert committees as Dr. F. Assaad (Director, Division of Communicable Diseases) explained to Dr. George Galasso (National Institutes of Health) in a later discussion related to influenza in 1983. See letter from Dr. Assaad to Dr. Galasso, dated 15 December 1983, WHO Archives, 12/181/3, “WHO Informal Consultation on the Clinical Use of Amantadine/Rimantadine in Influenza, Vienna, Austria, 26–28/8/1983,” Box. A.2138.

39. David Perlman, “The Flu Shot Program Poses a Dilemma,” *San Francisco Chronicle*, collected from Box 44, unlabeled binder, blank tab, RG 442, NARA's SE Region. Pencil notation “S.F. Chronicle, 4/5/[76].”

40. Ibid. See also anon., “Swine Flu Scare,” *New York Times*, 3 July 1976, A20; and anon., “Light on Swine Flu,” *New York Times*, 20 July 1976, A30.

7-8 APRIL 1976 WHO INFLUENZA EXPERTS MEETING

Influenza expert meetings at the WHO tended to be sober, scientific affairs with the assembly considered a gathering of equals. One participant from these 1970s meetings stated that the discussion usually revolved around technical issues like “discussing the antigenic relationship in the hemagglutinin inhibition test between strain so-and-so and strain so-and-so.”⁴¹ This emergency expert meeting would be playing out in a much more politically charged atmosphere. Some prominent experts were beginning to question how dangerous the new influenza strain might be while the largest benefactor of the WHO had already initiated a large-scale program to inoculate all its citizens.

There was no doubt over the purpose of the WHO meeting, which included influenza experts from thirteen nations in addition to experts from the WHO, the United States, and the UK.⁴² The meeting, as Dr. L. Bernard (Assistant Director General of the WHO) pointed out to the experts, was called because “The Member States of the WHO are asking for our guidance on several problems connected with appearance of the New Jersey strain of influenza virus and we would appreciate having your advice on these matters.” Dr. Bernard acknowledged that the new influenza strain A/New Jersey was a concern both because of “its spread from man-to-man” and “its antigenic relationship to the swine influenza-like virus which caused the 1918 pandemic.” Bernard thanked the CDC for helping the WHO fulfill its primary mission in the influenza program which, according to him, was “to detect as early as possible a drift or shift in the influenza virus and to make the new strain available on a world-wide scale for vaccine production as the need arises.” Bernard then issued a curious caution to the delegates, but apparently one they took to heart. Bernard enjoined the assembled experts to remember that “It should not be overlooked that countries in the developing world have no facilities for vaccine production.”⁴³ Bernard’s caution highlighted political concerns in this scientific meeting.

41. Claude Hannoun, interview with the author, 21 August 2007.

42. See “List of Participants,” attached to “Draft Agenda,” Box 32, unlabeled folder T-1 (3), RG 442, NARA’s SE Region.

43. “Opening of the Consultation on Influenza, Geneva, 7-8 April 1976, by Dr. L. Bernard Assistant Director General,” Box 32, unlabeled folder T-1 (3), RG 442, NARA’s SE Region.

Following the opening address, the first order of business for the WHO Consultation delegates was the appointment of officers. At this experts meeting V. M. Zhdanov (USSR) was elected as Chairman and Walter Dowdle (United States) and H. Bijkerk (Netherlands) were appointed as *Rapporteurs*. As Walter Dowdle described it:

Such ad hoc meetings are generally very informal and considered by WHO as a gathering of experts (consultants) and do not constitute a formal advisory committee. Thus, recommendations are not binding. No votes are taken. The person responsible for writing up WHO ad hoc meeting conclusions is the 'elected' rapporteur, with input from the chair, the secretariat, and often those representing opposing points of view. The draft conclusions and recommendations are presented to all participants at the conclusion of the meeting; with modifications accepted from the floor ... the final product is approved by the rapporteur and chair.⁴⁴

After the election of officers, the group adopted the agenda, which was followed by a review of surveillance data on influenza outbreaks.⁴⁵ Several nations were experiencing elevated influenza rates, but thus far no swine strains had been uncovered. The morning session of the meeting closed with a survey of the discovery of Swine Flu, the intense epidemiological investigation and the rationale for—and plan of—the vaccination program of the United States presented by J. Donald Millar, Director of the Bureau of State Services for the CDC. The program that Millar described was expensive and complex and one that faced enormous time pressures. The United States would need to develop a vaccine, test it, manufacture it in large quantities, distribute it equably around the nation, and deliver it into the arms of every citizen before (or during) the upcoming influenza season that could begin as early as September. The influenza experts broke for lunch pondering the fact that the

44. Walter Dowdle, email to author, 25 March 2007. For another description of the format of expert meetings at the WHO, see David Tyrrell and Michael Fielder, *Cold Wars: The Fight against the Common Cold* (New York: Oxford University Press, 2002), 170–76.

45. The following account of this meeting is drawn from Walter Dowdle's handwritten notes unless otherwise noted. "World Health Organization Consultation on Influenza Geneva, 7 and 8 April 1976, Report to the Director-General (Vir/76.4)," Box 32, unlabeled folder, T-1 (3), RG 442, NARA's SE Region for report and Walter Dowdle's handwritten notes from Box 32, unlabeled folder, T-1 (3), RG 442, NARA's SE Region. The author has conducted an interview with Walter Dowdle to confirm and clarify the account of the meeting, 26 May 2005.

United States had determined that A/New Jersey posed a sufficient threat to authorize a crash immunization program to inoculate the entire U.S. population.

The vaccination program outlined by Millar detailed the scientific assessment of the risk posed by the new strain and of the capacity to do something to mitigate that risk. The USPHS believed that it could vaccinate its entire population of 220 million people prior to the onset of pandemic influenza in the fall, and in this estimate they were substantially correct. Despite a series of delays caused by a mix of legal, legislative, and administrative problems, which held up full-scale production for several months, U.S. manufacturers produced over 156 million doses prior to the 16 December 1976 moratorium on the program.⁴⁶

The capability of other nations to copy the program outlined by the United States is a matter of some dispute. The earliest overall census of the productive capacity of influenza vaccine manufacturers dates only from the year 2000 and estimates from influenza experts involved in the decisions of 1976 show some variability in discussing vaccine productive capabilities.⁴⁷ Many of the developed nations possessed the technical capabilities to manufacture inactivated influenza vaccine and several had created at least some vaccines in response to the 1957 and 1968 pandemics. Walter Dowdle believed that in 1976, several Western European nations, Australia, and Japan possessed the capability to mount large-scale (if not universal) campaigns, and there is some evidence to bolster this assertion. Japan had been inoculating twenty million school children a year with influenza vaccine since 1973. Claude Hannoun, head of the laboratory at the WHO Collaborating Centre for Respiratory Viruses in 1976, estimates that French vaccine manufacturers could

46. CDC report for the Special Meeting 7 February 1977, called by Joseph Califano, Secretary of Health, Education, and Welfare, "Center for Disease Control Handout 1, February 7, 1977, Distribution of Influenza 'A' Vaccines," [Report cover page not included], received from the Centers for Disease Control in response to Freedom of Information Request (06-0781) dated 4 January 2007, in possession of the author.

47. "Global Distribution of Influenza Vaccines, 2000-2003," *Weekly Epid. Rec.*, 2004, 79, 366-67. Although the quantity of vaccine produced in 2000 was more than twice that produced a decade before (David Fedson, unpublished observation), there is no evidence to suggest that there has been a significant change in the nations producing vaccine. Estimate of previous vaccine production from David S. Fedson, "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development," *J. Public Health Pol.*, 2005, 26, 4-29, 8.

produce between four and six million doses in a normal year of vaccine production but could have tripled that output “in case of a very severe situation” by producing a monovalent vaccine. This level of production could have vaccinated up to 50–60% of the French population. In addition, the Italian government had informed the pharmaceutical house SCALVO that they intended to embargo all their Swine Flu vaccine (estimated at ten million doses) if a pandemic arrived, an estimate Hannoun thinks was “probably [a high] figure, but it’s not impossible.”⁴⁸

Other public health experts doubted the ability of other nations to mount large-scale campaigns, at least on a crash basis. For David Sencer, Director of the CDC from 1966 to 1977, the problem was not technical capabilities but infrastructure. U.S. manufacturers dominated the global market for inactivated influenza vaccines, partly because the CDC had been recommending yearly vaccines for those deemed ‘high risk’ (over the age of sixty-five or with chronic lung ailments) since 1960. “Flu was not a major vaccine anywhere other than in the United States.” Producing flu vaccine requires a steady supply of fertilized chick eggs and a sterile environment. In order to begin rapidly producing vaccine, “it takes buildings . . . it takes eggs . . . you don’t build those overnight.”⁴⁹

A similar point about the difficulties of rapidly ramping up vaccine production was made by Ian Furminger, who was head of Research and Development and Production Manager at Evans Medical, the Glaxo subsidiary that manufactured virtually all the influenza vaccine in the UK in 1976. Evans Medical produced just over a million doses a year of influenza vaccine for the domestic market in the mid-1970s. On a crash basis, Furminger estimated that Evans might have been able to increase production to around three million doses by producing only a monovalent vaccine and by

48. Walter Dowdle, personal interview, 26 May 2005; letter from Hideo Fukumi to Dr. W. Chas. Cockburn, Chief Medical Officer, Virus Diseases, World Health Organization, dated 20 July 1973 enclosing a report “Recent Influenza Epidemic of the New Type B in Japan,” WHO Archives 12/442/2 (72–73), “Information on Influenza Incidence 1/7/1972–30/6/1973, Jacket 2,” A.0525; Claude Hannoun, personal interview, 23 August 2007; and J. Lyle Conrad’s letter to “Director, Immunization Division Bureau of State Services, dated April 23, 1976,” Box 37, file titled “Swine Influenza National Influenza Immunization Program (NIIP) 1976–Correspondence,” RG 442, NARA’s SE Region.

49. David Sencer, personal interview, 9 May 2007.

running the factory around the clock. The lack of facilities prevented any greater level of production. "It's very difficult to rack up your production, mainly because you don't have the incubators in which to put the eggs," he explained, and there was also the problem of purifying the egg material, as "you have got to have centrifuges to purify it." Furminger stated that Evans did not have excess unused capacity and believed that other European manufacturers had similar yearly production rates and similar limitations on capacity.⁵⁰

Producing the inactivated flu vaccine on a large-scale was only one of the requirements for mounting a vaccination campaign. Such an effort would also require that the vaccine be efficiently and equably distributed and injected into the arms of citizens. Overwhelmed distribution systems had contributed to the failed vaccine campaigns of 1957 and 1968. J. Donald Millar was the man charged with implementing the National Influenza Immunization Program from the CDC, and he believed that even if other nations could produce large quantities of vaccine in short order (which he doubted), they would be unable to establish an effective distribution system. The CDC (and Millar) had experience with mass vaccination campaigns that others did not. The initial smallpox eradication campaign in West Africa had been run by the CDC as was a large measles inoculation effort, and following that, a large-scale measles vaccine campaign in the United States. According to Millar, in West Africa, "the population was a hundred and fifty million and we got over 80% of them vaccinated . . . this was jet gun, mobile teams, all of that. And . . . we'd done something not really dissimilar, in concept at least, with measles in this country. So we knew about mass campaigning. We had the jet guns and the know-how and a . . . thousand CDC employees out in the field [in the state health departments] whose specialty [is the] implementation of public health programs."⁵¹ In addition to spearheading the (successful) effort to eradicate smallpox in West Africa, the CDC provided the lion's share of those who coordinated the global effort of smallpox eradication under the auspices of the WHO.⁵² As Millar stated it,

50. Ian Furminger, personal interview, 30 October 2007.

51. J. Donald Millar, personal interview, 22 May 2007.

52. Millar, personal interview, 22 May 2007. In addition, see F. Fenner, D. A. Henderson, I. Arita, Z. Jezek, and I. D. Ladnyi, *Smallpox and Its Eradication*

many of those who got involved in the planning the Swine Flu campaign were old “African hands” and “loved international health and so were eager to get back into some mass campaigning.”⁵³

Perhaps the most compelling testimony of the capacity of nations outside the United States to produce inactivated vaccines comes from D. A. Henderson. Henderson, the famed head of the WHO global eradication campaign for smallpox, had a unique viewpoint on the WHO recommendation. Technically Henderson was “lent” to the WHO by the CDC to head the smallpox campaign. He remained on the CDC payroll and naturally retained close contact with the CDC. David Sencer said that Henderson “sort of acted as a U.S. conduit at WHO.”⁵⁴ Charles Cockburn, Director of Communicable Diseases and Henderson’s boss at the WHO, discussed the implications of A/New Jersey with Henderson, and Henderson was in the loop immediately upon discovery of the novel virus. In fact, Henderson served as Acting Head of Communicable Diseases when Cockburn was on leave. In that role, Henderson chaired a meeting of vaccine manufacturers from around Europe called in response to the discovery of A/New Jersey. As he recalls, “I remember this very well . . . from what the manufacturers that we were talking to could tell us, there was little production capacity . . . influenza vaccine was made in very small quantities, there was very little influenza vaccination going on in these areas at all, and the manufacturers were not in a position to greatly expand this capacity.”⁵⁵ These production and organizational differences formed the backdrop for the WHO recommendation and discussion.

WHO INFLUENZA EXPERT’S MEETING: AFTERNOON SESSION

In the morning session of the influenza expert’s meeting, the two U.S. representatives outlined the scientific evidence collected about the

(Geneva: World Health Organization, 1988), for an overview of CDC involvement in the smallpox eradication campaign.

53. Millar, personal interview, 22 May 2007.

54. Sencer, personal interview, 9 May 2007.

55. Henderson does not recall whether the meeting was part of the April 7–8 Consultation on Influenza Meeting (which he also attended) or a meeting held just prior to the influenza experts meeting. But he is certain that the meeting was to discuss European vaccine manufacturing production capabilities in response to Swine Flu in 1976. D. A. Henderson, personal interview, 26 July 2007.

events at Fort Dix and the resulting public health response the nation would pursue. The afternoon session would be dominated by the scientific evaluation of the new influenza strain by other influenza researchers and the public health options they were considering. The first speaker was Dr. M. Pereira (Virus Reference Laboratory, Control Public Health Laboratory, London, and the new co-Director of the World Influenza Center) who suggested that nations adopt the model prepared for the UK.⁵⁶ The plan called for the incorporation of A/New Jersey vaccine into the current recipe for the next year's vaccine to be produced in the usual numbers. This low-key response was based on the fact that "a mass vaccine presented a problem—1) money; 2) mass vaccination."⁵⁷

Following the proposal for adopting the minimal UK approach, Geoffrey Schild reported on an experiment conducted by UK researchers Beare and Craig at the Common Cold Unit in Salisbury, UK.⁵⁸ The experiment infected six human volunteers with the A/New Jersey strain and then tracked the progress of their infection. Schild reported the results as "1 moderate case, 2 mild cases and 3 subclinical. All secreted virus by 3–4 [days]."⁵⁹ The timing of this report by Schild within the meeting was very suggestive. On the heels of discussing the limited UK response to the novel strain, Schild described an experiment that seemed to demonstrate that A/New Jersey prompted a very mild case of the flu. The juxtaposition of evidence that this novel virus caused a mild illness bolstered the decision of the British to take a very limited approach to A/New Jersey, which stands in sharp contrast with the U.S. decision to mount a massive vaccination campaign.

The merits of the Common Cold Unit experiment were (and are) debatable. A laboratory setting cannot mimic a natural infection, plus the laboratory strain used was weaker than a naturally

56. Dowdle's notes from the Geneva meeting refer to "Peggy." He has subsequently identified "Peggy" as Dr. M. Pereira. Walter Dowdle, personal interview, 26 May 2005.

57. Walter Dowdle's handwritten notes on the Geneva meeting, 7–8 April 1976, from Box 32, unlabeled folder, T-1 (3), RG 442, NARA's SE Region.

58. This experiment was subsequently reported in *Lancet*. See A. S. Beare and J. W. Craig, "Virulence for Man of a Human Influenza—A Virus Antigenically Similar to 'Classical' Swine Virus," *Lancet*, 3 July 1976, 2, 4–5.

59. This description of the results is slightly different from the results reported in the *Lancet* article. See Beare and Craig, "Virulence for Man of a Human Influenza—A Virus Antigenically Similar to 'Classical' Swine Virus," 4–5.

occurring strain. Serial passage through the human population adapts the influenza virus to the human host and laboratory infections cannot replicate that process. As Walter Dowdle stated “it just simply isn’t the same as if you have millions of people infected with that same agent.” A point also made by eminent influenza expert Edwin Kilbourne who noted that emphasizing the lack of severity of infection among the six volunteers was “nonsense, nonsense . . . It’s not the same as sitting next to a cot with somebody sneezing in your face.”⁶⁰ In addition, the fact that the strains used to infect the volunteers had undergone passage through chicken eggs six times in preparation for infecting the six volunteers limited the value of the conclusions because this process furthered weakened the virus. Kilbourne, whose laboratory at the New York Medical College had created over thirty vaccine or vaccine-candidate reassortant strains, commented that “When a virus has been passed through an alien host [chicken eggs] like that,” it actually mirrored an old method of weakening a virus for use in a vaccine. Attenuated (weakened) virus vaccines were “based on the simple act of . . . serial passage in the egg. They weren’t temperature sensitive, they weren’t cold adapted [other methods to develop vaccine strains] or anything. They were just passages . . . if you passed it a few times you couldn’t infect anyone.”⁶¹

As the delegates began to discuss the WHO recommendation, they had a limited amount of information at hand. One was the epidemiological information provided by the United States that demonstrated person-to-person spread and that A/New Jersey was a novel virus, a situation tailor-made to create a pandemic. Second was an experiment that seemed to suggest that A/New Jersey prompted a mild course of infection. Pairing these results with the U.S. data elevated this limited experiment (six volunteers) to a status comparable with the extensive immunological and epidemiological examination conducted by the CDC. It needs to be noted that this is not to suggest that the delegates were shills for any type of political or policy decision, a point Walter Dowdle took great pains to emphasize. “I think that would have been absolutely

60. Dowdle, personal interview, 26 May 2005, and Edwin Kilbourne, personal interview, 20 January 2004.

61. Kilbourne, personal interview, 20 January 2004.

unacceptable and always had been and will be ... to carry the national policy on the international scene, and even though some people might want that to be done, nevertheless that just not the way to do business." Dowdle agreed with the suggestion that it was "science" under which they worked. However, it should be underlined that the results of the Common Cold experiment were actively promoted as conclusive. As Dowdle stated it, "It's very difficult to know ... what really would have happened based on a few volunteers. So I think whereas the British particularly—and a few of them pushed very hard—I think most of us felt like this was not a good idea or not really all that relevant."⁶² Also, vaccine manufacturers had informed them that they would not be able to substantially increase their inactivated vaccine production. In addition, no other cases of Swine Flu had been found, and the transmission of A/New Jersey in the camp had ended without intervention.

Another factor involved in crafting the WHO recommendation was the fact that the vast majority of nations would be unable to mount any sort of vaccine program on an emergency basis, and even some of the influenza experts at the Geneva meeting represented nations that could only produce a very limited amount of inactivated influenza vaccines for their citizens. For example, China, with its roughly one billion population, found it "difficult to make" killed virus vaccines and recognized that they "can not produce killed [vaccine] for all millions."⁶³ The difficulty in manufacturing inactivated vaccines lies with the process itself. Producing influenza vaccines was (and still is) a cumbersome process. It required identifying and distributing a vaccine strain, gathering sufficient materials for production (e.g., influenza vaccines were incubated in fertilized chicken eggs), then testing, deciding on dose strength, producing, bottling, and delivering to the purchaser. If the Chinese, and other nations, could not protect their citizens with killed vaccines, perhaps the solution lay with live-virus vaccines.

62. Dowdle, personal interview, 26 May 2005.

63. Dowdle ascribe these quotes to Dr. Cho [sic]. It is most likely Dr. Chang Yi-Hao, from the Vaccine Department of the Peking Institute of Biological Products, Peking China. However, it could be Dr. Kuo Yuan-Chi from the Institute of Epidemiology of the Chinese Academy of Medical Sciences, Peking China. Unless otherwise noted, the following quotes are from Walter Dowdle's handwritten notes on the WHO Consultation on Influenza Meeting from Box 32, unlabeled folder, T-1 (3), RG 442, NARA's SE Region.

In theory, live-virus vaccines are greatly weakened but still living strains that when inhaled generate an infection course that is so mild the inoculated can barely discern they are infected. However, the weakened virus is sufficiently robust to prompt powerful long-lasting immune system response. Live-virus vaccines were easier and cheaper to make (because the virus does not need to be inactivated and purified); easier to deliver (because the dose is inhaled rather than injected); and greater quantities could be produced (more vaccine doses could be produced per egg because the amount of material needed to inoculate someone was smaller than an injected dose). Because the virus mimicked the natural course of infection, there were some who thought the immunity produced by the live-virus vaccine would be superior to injected killed-virus vaccines. In the 1970s, those weakened live-virus strains were shaped to only replicate at low temperatures, thereby limiting their ability to reproduce in the warmer human body. Thus, cold-adapted viruses would minimize replication in the individual (making the infection shorter and milder) and prevent further transmission to others (because the virus would not reproduce effectively in the inoculated, there would be few copies of the virus made to infect others). These attenuated, cold-adapted live-virus vaccines promised much greater vaccine coverage and protection.

Live-virus vaccines held the potential for providing much greater coverage in a much shorter period of time, exactly what was needed to protect the public from an influenza pandemic. And, in fact, several Eastern Bloc nations had claimed successful and safe use of live-virus vaccines for many years. For example, the Soviet Union declared that they had been using live-virus vaccines without problems and with a high degree of immunization protection since 1957 and that “the best flu prophylactic is living vaccine.”⁶⁴ Several influenza experts outside the Eastern Bloc also believed that “only live-virus vaccines can provide a means of mass

64. Letter from V. Zhdanov, Director U.S.S.R. Influenza Centre to Dr. A. M. M. Payne, Chief, Section of E. E. Diseases, World Health Organization, dated November 1957 [received 12 December 1957], WHO Archives, I2/418/12, 23 (microfiche). Quote is from “Memorandum From: Professor Zhdanov, Deputy Minister of Health, To: Dr. Payne, Chief Section of E. E. Diseases, World Health Organization, dated 11 March 1958.” WHO Archives, I2/418/12, 25 (microfiche). The author thanks Helen Hundley for translating the second document.

immunity against new virus subtypes” although admittedly “the problem of producing them repeatedly and infallibly has not, however, been solved.”⁶⁵ In 1971, the WHO sponsored an “Informal Consultation on International Collaboration in Research on Live Influenza Virus Vaccines.” The “Report to the Director General” contained a summary of the discussion of the assembled experts. The conclusion of the report called for increased international collaboration on live-virus vaccine studies, but it also described a troubling aspect of live virus immunization. Under “Assessment of Attenuation,” point number 3 suggested that attenuated strains possess “no ability to spread from person to person and revert to virulence on passage,” but, as the report remarked, “there have been few attempts to study point number 3 and there are no agreed methods for measuring spreading ability.”⁶⁶ The incapacity to measure whether a live-virus vaccine strain would spread beyond the inoculated was a serious check to the practical use of live-virus vaccines, at least in the West.

The promise of live-virus vaccines was undermined by the high mutability rate of the virus. The vaccine strains were engineered to prevent or limit transmission from the inoculated to others. However, the vaccine virus strains were mutating beyond these limitations, resulting in continued chains of infections. The instability of the vaccine strains was a problem that U.S. and UK researchers had observed in their own experiments aimed at generating non-mutating live-virus vaccine strains. They had tried and failed to obtain samples of the Soviets live-virus vaccines in order to test independently whether the Soviets had really been able to solve these transmission issues.

By the early 1970s, it was becoming clear that, contrary to Soviet claims, live-virus vaccine strains might be persisting in the populace

65. Report by Dr. A. S. Beare on his “Visit to the Department of Epidemiology, School of Public Health, University of Michigan under the auspices of the World Health Organization,” attached to letter from A. S. Beare, Medical Research Council and Department of Health and Social Security, MRC Common Cold Unit to Dr. W. C. Cockburn, Virus Diseases Unit, dated 5 July 1972, WHO archives 12/445/6, “Collaborative Study on Live Influenza Vaccine Strains,” A.526.

66. “Report to the Director-General on an Informal Consultation on International Collaboration in Research on Live Influenza Virus Vaccines, Geneva, 4 and 5 October 1971,” WHO Archives, 12/445/6, “Collaborative Study on Live Influenza Vaccine Strains,” Box A.526. There is no way to tell from this source, what, if any, importance was attached to this observation at this time.

of the Eastern Bloc nations. For political reasons, the Eastern Bloc nations had not provided influenza virus samples until the late 1960s. In a letter dated 16 September 1971 to Dr. Z. Nikolova, National Influenza Center Bulgaria, Geoffrey Schild wrote that the 1964-like strains isolated by Nikolova in 1969 could very well be re-isolation of the vaccine strain and "the possibility that attenuated vaccine strains may persist in the community for considerable periods of time has, of course, important implications in the surveillance work carried out by WHO."⁶⁷ In a later letter sent to Dr. Cockburn referring to the continued persistence of older strains in Eastern Bloc countries and marked "In Confidence," Schild stated that "It may be that the 1972 variant is persisting far longer in U.S.S.R. and [E]astern Europe than in other areas. However, an alternative explanation is that live attenuated vaccine strains are being re-isolated in these areas. It will not be easy to establish if this is the case but I will request further isolates for study and also look into the question of whether the strains possess any 'markers' which would help in this characterization."⁶⁸

Live-virus vaccines offered a further potential danger beyond serial transmission of a vaccine strain and possible reversion to virulence. Because the virus was a living strain, it could conceivably recombine with another strain to create a hybrid with elements of both parent strains. In 1976, some influenza researchers feared that if a live-virus vaccine (adapted for human infection to maximize vaccine effectiveness) combined with a naturally occurring swine influenza infection, there was no predicting what virulence or infective capacity the new virus would exhibit.⁶⁹ Widespread use of

67. Letter from G. C. Schild to Dr. Z. Nikolova, National Influenza Centre, Bulgaria, dated 16 September 1971, WHO Archives, I2/442/2 (71-72) 1 (microfiche).

68. Letter from Schild to Cockburn, dated 19 July 1974, WHO Archives, I2/442/2 (73-74), "Information on Influenza Incidence 1/7/73-30/6/74 Jacket 2," Box A.0525.

69. The unstable nature of live-virus vaccines still concerns some influenza experts today. There are several sets of dangers with live-virus vaccines. First, the introduction of the vaccine produces a real, albeit mild, infection by the influenza virus. This presents the opportunity for secondary bacterial infections because the virus is replicating in the respiratory tract. Second, the inoculated person sheds real live virus and poses a threat to others, especially immunosuppressed people. In tests up to 50 percent of these shed viruses represent reassortments of the original vaccine strains. This is dangerous both because two avirulent viruses can combine to form a virulent virus and because the virus could reassort with an emerging pandemic strain providing it with a heightened capacity for infection or replication. Information from Edwin Kilbourne, personal interview, 20 January 2004.

unstable live-virus vaccines could provoke the very pandemic they were designed to avoid, making the cure worse than the disease. This potential live-virus vaccine danger was recognized by manufacturers as well as by health officials.⁷⁰

From this mix of competing and contradictory information—alarming and calming scientific evidence related to the new virus; contending programmatic responses ranging from a massive vaccination campaign to a low-level inclusion of a Swine Flu strain in a normal production level; uneven production and distribution capabilities; and a potentially dangerous live-virus solution—the drafting committee would have to construct an official WHO policy. In addition, the experts had to consider the public response to any recommendation which as French expert Claude Hannoun stated could range from “panic” to a “lack of interest.”⁷¹ The tug and pull of scientific and political interests in crafting the WHO policy are visible in the drafts and final versions of the document, which culminated in a recommendation that adopted a milder depiction of the potential pandemic threat of the new virus, and a low-key response of “watchful waiting.”

WHO DRAFTS AND RECOMMENDATIONS

The official recommendation produced by the influenza experts for the Director-General of the WHO at the 7–8 April 1976 meeting went through several drafts before the final version was delivered. The resulting depiction of the potential pandemic threat of the new viral strain and the recommended course of actions national health organizations should pursue were modified in the process. In the initial draft of the Consultation on Influenza Recommendation, the first suggested course of action included both a calming and cautionary depiction of the virus.

70. See letter dated 4 February 1976 from Maurice R. Hilleman, Director, Virus and Cell Biology Research, Merck Institute for Therapeutic Research to John R. Seal, Acting Deputy Director National Institute of Allergy and Infectious Diseases, National Institutes of Health, regarding the 20 January summary of the live-virus vaccine meeting. Obtained via Freedom of Information Act request (case no. 28820) to National Institute of Allergy and Infectious Diseases for information related to the “Swine Flu Program of 1976,” material titled “Box 6, Book 42 containing workshops/meetings and fact sheets” in possession of the author.

71. Walter Dowdle’s handwritten notes on the Geneva meeting, 7–8 April 1976 from Box 32, unlabeled folder, T-1 (3), RG 442, NARA’s SE Region.

Since it is by no means certain that A/New Jersey strains have the capacity to cause a widespread disease, there is no justification for public alarm. In particular it should not be inferred that the present situation is the same as that which existed at the beginning of the 1918 epidemic. Nevertheless health authorities would be wise to prepare contingency plans for a possible pandemic ... [and] the adaptation of existing health services to an exceptional situation.⁷²

Several recommendations followed that emphasized heightened surveillance and increasing or initiating production of killed-virus Swine Flu vaccines. Point 7 addressed the concern over the use of live-virus vaccines. "Extreme caution is necessary if live attenuated vaccines containing A/Swine-like strains are used for experimental purposes because of the danger of possible reversion to virulence and spread to susceptible human or animal hosts." Dowdle also added in the statement that there was a danger of "recombination with other influenza" with the use of live-virus vaccines.⁷³

The tone of this first draft was forthright about the potential danger of a pandemic, but cautious so as not to cause a panic. The conclusion of this draft was that nations will want to get ready for a potential pandemic of Swine Flu, and that this build-up must begin immediately to address an "exceptional situation." Each nation would respond according to its capabilities, but they should not wait for additional cases to begin making arrangements. This reasoning of immediate program formation was based on the failed vaccination campaigns of 1957 and 1968 when nations had been unable to produce or distribute a protective vaccine before the pandemic peaked.

The second draft of the recommendation from the WHO influenza experts, titled "Draft Final Report of the Consultation on Influenza, Geneva, 7 and 8 April 1976," summarized the relevant scientific information considered by the experts.⁷⁴ In this and

72. This, and the following quotes come from the "Consultation on Influenza, Report—First Draft, Recommendations," with Dowdle's penciled editing notes, Box 32 unlabeled folder T-1 (3), RG 442, NARA's SE Region unless otherwise noted.

73. As Dowdle later explained, this concern of live virus use was not a theoretical issue. He reports that this "extreme caution" on using live-virus vaccines was inserted because of reports that several investigators outside Western Europe intended to develop and test such vaccines. Walter R. Dowdle, "Influenza Pandemic Periodicity, Virus Recycling, and the Art of Risk Assessment," *Emerg. Infect. Dis.*, 2006, 12, 34–39, 38, available from www.cdc.gov/eid.

74. Unfortunately, the first draft of the Consultation Report only included the "Conclusions and Recommendations." Presumably, the additional information existed at

subsequent drafts, the WHO experts consciously sought to tone down the alarming nature of the Fort Dix outbreak.⁷⁵ This toning-down process took several forms. As noted previously, Assistant Director General Dr. L. Bernard had expressed the purpose of this special meeting as addressing the Fort Dix outbreak and its demonstration of “man-to-man” spread. Only a summary of Dr. Bernard’s address was released, and this important phrase was removed from his speech. The edited phrase read “The appearance of a new strain of Influenza A at Fort Dix, New Jersey in the United States of America in February this year and its antigenic relationship to the virus which caused the 1918 pandemic has caused much concern all over the world.”⁷⁶ Another example of a mild depiction of the Fort Dix outbreak was the description of the U.S. Army’s investigation at the camp. The U.S. Army’s influenza experts had concluded that A/New Jersey had been passed person-to-person, resulting in an estimated five hundred cases. The WHO report stated this epidemiological conclusion as “Approximately 500 swine influenza-like infections may have occurred during the 4–5 week period.” In addition, a commentary was added to the conclusion of the Fort Dix investigation. “Previous strains leading to a pandemic like the 1957 and 1968 strains were preceded by small outbreaks. Though the Fort Dix episode occurred in the influenza season, no such other outbreaks have been reported so far.”⁷⁷

Immediately following the report on the investigation at Fort Dix was the summary of the Common Cold Unit experiment

one time as the “Conclusion and Recommendations” section was paginated 11 and 12. Therefore, I cannot compare what changes may have been made in the characterization of the information. Unless otherwise noted, the following quotes are taken from this later draft, “Consultation on Influenza Geneva 7 and 8 April 1976, Draft Final Report,” Box 32, unlabeled folder T-1 (3), RG 442, NARA’s SE Region.

75. A perception validated by Walter Dowdle. Walter Dowdle, personal interview, 26 May 2005.

76. The original sentence read [with the excised words in bold] “The appearance of a new strain of influenza A at Fort Dix, New Jersey, in the USA in February this year caused some concern about **its spread from man-to-man because** of its antigenic relationship to the **swine influenza-like** virus which caused the 1918 pandemic.” “Opening of the Consultation on Influenza, Geneva, 7–8 April 1976, by Dr. L. Bernard, Assistant Director General,” Box 32, unlabeled folder T-1 (3), RG 442, NARA’s SE Region. It is worth noting that the Common Cold Unit experiment could be construed as easing concerns that A/New Jersey might have the same mortality as Spanish Flu.

77. “Consultation on Influenza Geneva 7 and 8 April 1976, Draft Final Report,” Box 32, unlabeled folder T-1 (3), RG 442, NARA’s SE Region.

which traced the result of A/New Jersey infections in six volunteers. The worst course of infection had moderate clinical symptoms, and three were listed as having no symptoms at all. The inclusion of this limited experiment made it appear much more conclusive than most influenza experts were willing to concede.

Simultaneous with this trend of de-emphasizing the pandemic potential of A/New Jersey was increased emphasis on surveillance evidence and the power of the WHO surveillance system. For Walter Dowdle, the absence of additional cases was suggestive. "To me, the next data you were waiting for is does it spread . . . you are already going from January into February and to March and to April and so on, that's getting quite a way down the line without any evidence of spread. And so you have to say that no matter how bad your surveillance is, you should have picked up something."⁷⁸ Surveillance had not detected any additional cases. Therefore, the official version of the "World Health Organization Consultation on Influenza Geneva, 7 and 8 April 1976 (Vir/76.4)" stated that although vaccines are "useful in preventing the disease in individual cases, and in limiting spread in well-vaccinated communities, [they] will not control or prevent the spread of influenza in the world. Therefore, *if extensive epidemics do occur* other measures will have to be taken."⁷⁹ Under its recommended options, the WHO suggested as its first choice "storage in bulk" for those nations who would produce killed A/New Jersey vaccine. This option was moved from "c" to "a" in the final version. This option suggested that information from "the surveillance network" might provide definitive evidence for crafting a crash immunization campaign. The WHO recommendation had consciously evolved into one that downplayed the pandemic potential of A/New Jersey, and one that suggested greater reliance upon the surveillance system. This toning-down process also took place in the press release drafted by the expert committee including substituting the direct phrase "person-to-person" with the indirect "among humans." However, as Dowdle recalled "I don't remember a particular big fuss over that and it could be that it was phrased in such a way

78. Walter Dowdle, personal interview, 26 May 2005.

79. Emphasis mine. This and the following quotes are taken from "World Health Organization Consultation on Influenza Geneva, 7 and 8 April 1976, Vir/76.4" from Box 32, unlabeled folder T-1 (3), RG 442, NARA's SE Region.

that ‘person-to-person’ wasn’t essential . . . I just don’t remember to be honest.” Dowdle also expressed the view that he “totally agreed with the outcome” of the Geneva meeting and that Geneva “reflected my feeling as well.”⁸⁰

The influenza experts at the 7–8 April meeting evaluated the same fundamental scientific evidence that had prompted the U.S. decision to begin a massive vaccination campaign just two weeks previously. The only new evidence presented at the WHO meeting was the Common Cold Unit experiment, an experiment that many influenza experts dismissed as possessing limited value, and that the admittedly spotty surveillance system had not detected any more cases of Swine Flu. Some U.S. public health officials maintain that no other nation mounted a vaccination campaign similar to the U.S. program because no other could mount such a program.

As we have seen, in 1976, the United States was unique in possessing both the productive capacity and the logistical experience to attempt a large-scale vaccination campaign. J. Donald Millar stated that “at that meeting in Geneva . . . nobody wanted to go our route, but nobody thought they could go our route.” As D. A. Henderson colorfully stated it in response to the question of whether the experts had a sense of production capacity, he replied “We got a very good sense and the capacity was zilch.”⁸¹ Millar’s and Henderson’s recollections of the limitations other nations had in producing vaccine are validated by contemporaneous, or nearly contemporaneous notes and correspondence from the two men. As U.S. delegate to the experts’ meeting, Millar jotted down some comparisons of the U.S. position and WHO position following the April 7–8 influenza expert’s meeting. It was the U.S. premise that “vaccine probably can be made for all in the U.S.” The WHO attitude was “In the rest of the world NO WAY vaccine can be made for more than a few developed countries.” The U.S. possessed a “delivery system probably adequate to deliver before transmission season.” The WHO attitude was “Throughout the world, NO WAY vaccine could be delivered even if available.”⁸² D. A. Henderson summarized the constraints on

80. Dowdle, personal interview, 26 May 2005.

81. Millar, personal interview, 22 May 2007, and D. A. Henderson, personal interview, 26 July 2007.

82. J. Donald Millar, Copy of notes faxed to author, 24 May 2007. Emphasis in original. In possession of the author.

other nations in their response to Swine Flu in a 12 March 1979 letter to Professor Richard E. Neustadt, co-author of a book critical of the Swine Flu program. Henderson wrote.

If the pandemic materialized and especially if the case-fatality rates were high, the only vaccine available would be in the U.S. and limited amounts in some European countries. The inevitable scenario of confrontation between countries with and without vaccine was not one which any of us could sanguinely look forward to. This was a problem of real concern without apparent solution. We did convene an international group and made available all of the facts. They had the option of "viewing with concern" [and] alarming their own population with limited capacity to respond with vaccine. Or, as they elected to do, they highlighted the fact that the disease was mild, they would commence to produce vaccine to the extent possible and would "wait and see." In retrospect, the decision of the international committee may be viewed as sound and rational when, in fact, I know the decision to have been borne of necessity.⁸³

"LESSONS" OF THE WHO DECISION

Retrospective critiques of the Swine Flu Program in the United States have suggested the U.S. health officials quickly settled on the decision for a vaccination program and never revisited that decision. Stated another way, what could be done shaped the evaluation of what should be done. WHO health officials faced a different set of problems. With the possible exception of France and Japan, no other nation could rapidly produce and distribute inactivated influenza vaccines. A potential solution to this production problem lay in the use of live-virus vaccines that were easier to manufacture, effective dose levels could be produced in greater quantities, and inoculation of citizens was simpler. However, live-virus vaccines were unstable and might combine with wild strains, creating a dangerous hybrid virus and therefore should not be used. Operating within these constraints, the influenza experts consciously or unconsciously downplayed the pandemic potential of A/New Jersey. The revised interpretation of the new virus was shaped by fears of provoking a panic.

83. Copy of letter from D. A. Henderson to Professor Richard E. Neustadt, dated 12 March 1979. Copy sent via email from David Sencer, 9 May 2007, in possession of the author.

In conjunction with this milder depiction of the potential danger of this new viral strain, the influenza experts de-emphasized the need for a special vaccination effort, or even injection of a protective vaccine against A/New Jersey at all. The first recommended course of action for nations that produced an inactivated vaccine to protect against the new virus was "storage in bulk." The second recommended course of action was adding the vaccine to the "currently recommended vaccine." The third option was use as a "monovalent vaccine."⁸⁴ Such a recommendation stood in stark contrast to the U.S. decision which had recommended widespread use of the vaccine as a monovalent injection and the protection of every U.S. citizen. Preparation for the U.S. program commenced immediately with the shots to be distributed in the fall. For the WHO recommendation, the trigger for distributing the vaccine, or even initiating production of the vaccine, would come from the influenza surveillance system.

The WHO emphasized greater reliance upon the surveillance system because of the reluctance to suggest creating vaccination campaigns as its stated recommendation. However, there were two major problems with influenza surveillance. The first was that surveillance coverage was uneven, a point recognized by influenza experts at an international meeting on combating influenza held just a few months prior to the April Geneva meeting. Second, surveillance was designed to sample the broad sweep of influenza activity. The WHO suggested relying upon the surveillance system to help nations craft a vaccination decision, but surveillance was unlikely to catch the virus until it was spreading epidemically. Also, the surveillance system depended upon reports from the individual national health programs that either could not or would not report influenza activity in their nation.

Therefore, it was highly unlikely that the influenza surveillance system would have detected the spreading virus before it had prompted regional epidemics. Pandemic spread would have inevitably followed these regional outbreaks. Spanish Flu's second wave encircled the globe in four months in 1918, and in 1957 and 1968, the timeframe from discovery to epidemic peak was less than

84. The following quotes and summary are drawn from World Health Organization, "Consultation on Influenza, Geneva, 7 and 8 April 1976," Report to the Director-General, Vir/76.4, obtained from the WHO Library, Geneva.

six months. Since the influenza experts believed that a pandemic was a possibility—although there was widespread disagreement over how likely a possibility that was—it is fair to posit what would have happened if A/New Jersey had prompted a pandemic spread. Nations that had followed the WHO recommendation and had developed a stockpile program with vaccine stored in bulk would have been hard pressed to distribute and deliver a preventative vaccine. Nations that had waited for additional information such as additional cases or local epidemics to begin production would have had no chance of producing and distributing a vaccine in time. Because of fears of provoking a panic or of prompting the use of unstable live-virus vaccines, the WHO recommendation toned down the portrayal of the Fort Dix outbreak and emphasized reliance upon the surveillance system, reliance the surveillance system did not warrant. The WHO recommendation from the influenza experts recreated the scenario of 1957 and 1968 when vaccination programs failed to protect citizens from the respective pandemics because protective vaccines could not be produced and distributed prior to the pandemic peak of the virus.

In the present day, predicting the pathways of infections and forecasting pandemic spread is still enormously difficult and frequently must be made on confusing and contradictory information. Crafting public health policy remains a delicate balance of what should be done and what can be done. Extolling public policy is further complicated for the WHO whose guidance is implemented by national health organizations and is subject to the ability or willingness of these organizations to work toward those goals. The subtle pressure to create an endorsement of a public health program that appeals to a broader constituency of health organizations with uneven resources can shape perceptions of disease threats, especially since these threats are rarely clear-cut. In 1976, the WHO recommendation of watchful waiting turned out to be the proper course of action; Fort Dix was an anomaly and no pandemic appeared. However, upon closer examination, it is not clear what other option the WHO influenza experts could have recommended. Critics of the Swine Flu Program have suggested that the scientific approach to the virus was shaped by the fact that the United States could mount a massive vaccination campaign. It seems that the WHO's scientific interpretation of the pandemic potential of the virus and suggestion of possible responses for national health programs was shaped by the opposite conclusion.

ACKNOWLEDGMENTS

The author gratefully acknowledges the assistance of the staff at the National Archives and Records Administration, Southeast region, Tom Love and the Centers for Disease Control, the Food and Drug Administration, the National Institutes of Allergy and Infectious Diseases, Marie Villemin at the World Health Organization Archives and Avril Reid at the World Health Organization library (Geneva) for providing archival material; Walter Dowdle, David Sencer, J. Donald Millar, Sir John Skehel, Claude Hannoun, and Ian Furminger for making themselves available for interview; Patrick Manning, Clay McShane, and Edwin Kilbourne for their assistance in processing this information; Anthony Penna, William Vanderburgh, Day Radebaugh, and Jodi Dehner for comments on previous drafts of this article and Helen Hundley for translations of Russian language documents. The author would also like to acknowledge the editorial comments of Margaret Humphreys and of two anonymous reviewers which substantially helped sharpen the manuscript. Omissions and errors remain the sole responsibility of the author.

FUNDING

The author thanks Wichita State University for awarding me a Fairmount College of Liberal Arts and Sciences 2007 Summer Support Fellowship to offset travel to the World Health Organization.