Swine Flu: Were the Three Deaths in Pittsburgh a Coincidence?

Pittsburgh. The odds against it happening by chance seemed enormous. Three elderly individuals went to the same public health clinic here to receive influenza shots on 11 October. They were inoculated within an hour of each other from the same lot of vaccine. And all died from 1 to 6 hours later.

The unusual cluster of deaths triggered a nationwide spasm of alarm that threatened to disrupt the massive campaign now under way to immunize the American population against "swine flu." The Allegheny County Health Department, which serves Pittsburgh and the surrounding area, closed down all its influenza immunization clinics pending an investigation of the situation. Several other states and local jurisdictions followed suit. And the press began reporting scattered deaths that had occurred after immunization in other areas of the country.

But a joint federal-state investigation of the Pittsburgh deaths turned up no evidence to incriminate the vaccine or the method of administration. The official explanation of the three deaths, Frank B. Clack, director of the county health department, told a press conference here, is that they were a "coincidence"—an unusual cluster of deaths that may have had a temporal relationship with the influenza program but were not caused by it. Soon the panic subsided, the clinics reopened, and President Ford ostentatiously received a flu shot to dramatize his confidence in the safety of the vaccine.

Still, some nagging doubts remained. Was it really a coincidence? Or could an as yet undetected common thread tie the three deaths together? Conclusive answers are not available, partly because the investigation failed to explore certain factors that might conceivably have contributed to the deaths, and partly because a running battle between the county coroner and health officials at the local, state, and federal levels has tended to confuse the issue. The coroner's persistent criticisms may even have goaded the county health department into adopting corrective measures that bear little proven relevance to the circumstances surrounding the three deaths.

The coroner, Cyril H. Wecht, is the only public official who has persistently challenged assurances that the immunization campaign was not responsible for the three deaths. A flamboyant politician with medical and law degrees and a penchant for making headlines, Wecht complained in an interview that federal and state health officials "casually and completely" dismissed the possibility that "something went wrong" in the campaign even before the final results of the investigation were in. But Wecht acknowledges that he has no evidence to indicate that the deaths were other than coincidental—just a theory or two that he would like explored more fully. "I don't understand the rationale and thinking of people who don't want to look further and just say it was coincidental," Wecht says. "It may be. But I'm not sure of it."

The three who died all visited the health department's South Side clinic, a one-story brick building at 1016 East Carson Street that serves an area of Pittsburgh inhabited by various "white ethnic" groups, many of whom work in the nearby steel mills. On the day in question, the clinic was inoculating high-risk individuals—the elderly and those suffering from chronic diseases—with a bivalent vaccine designed to protect them from both swine flu and the A/Victoria strain of flu.

The three deaths were not the only serious adverse reactions to occur among the 1242 individuals who received shots at the clinic that day. At least two other individuals were deemed ill enough to warrant calling an ambulance. All five of the affected individuals appear to have been at the clinic within the span of an hour, though the precise times of arrival and departure are a little uncertain since they are based largely on the memory of relatives who accompanied the victims.

The first individual to suffer ill effects was a 64-year-old woman who became weak, pale, and dizzy after inoculation. The nurses called an ambulance, but the woman refused to accompany the medics to the hospital. Instead, she was helped home and, when called by nurses the next day, was back to normal.

The second victim was a 75-year-old woman—Mrs. Julia Bucci—who hobbled into the clinic with the help of her daughter, her husband, and a tripod cane. She had a history of heart problems, hypertension, obesity, diabetes, and lung ailments. Within minutes after getting her shot, she complained of feeling weak, became pale, her lips turned blue, and she had difficulty breathing. Nurses administered oxygen and called the ambulance. She seemed to revive and was talking to people as she left for the hospital. But about an hour later she died at the hospital. The official cause was arteriosclerotic cardiovascular disease and acute pulmonary edema.

The third person to react was an 81-year-old woman who had suffered chest pains earlier that very morning and had taken two nitroglycerine tablets before leaving for the clinic. While Mrs. Bucci was being rushed to the hospital, this next woman became faint, was given ammonia inhalant and oxygen, and was also rushed to the hospital, where she was examined in the emergency room, found normal, and discharged.

The other two victims showed no signs of ill effects at the clinic, where all vaccine recipients were held for observation for about 15 minutes after inoculation. One was Charles Gabig, 71, who went shopping with his wife right after their injections. While in the grocery store he complained of pains in both arms. He immediately went home, lay down in bed, and shortly thereafter was found dead. Death was attributed to a heart attack, blood clot, and other cardiovascular problems.

The final victim was 74-year-old Ella Michael, who had a history of cardiovascular disease and emphysema. She felt fine immediately after the injection, but complained of blurred vision on the way home and said her jaws hurt. Later that afternoon, perhaps 6 hours or so after the inoculation, she died in her chair. The cause was arteriosclerotic cardiovascular disease and severe pulmonary emphysema. Ironically, her personal physician was Roy L. Titchworth, chairman of the Allegheny County Board of Health, a heart and lung specialist.

Autopsies were performed on all three victims by the county coroner's office, but nothing abnormal was found beyond the chronic disease conditions which were deemed the cause of death. There were no signs of anaphylactic shock, the most likely cause of rapid death after an inoculation.

Even before all the autopsies had been completed, epidemiologists from the federal Center for Disease Control in At-

lanta took a night flight to Pittsburgh, arriving at 3:20 a.m. the morning after the deaths had occurred. They promptly launched an investigation, with extensive help from personnel of the county health department. Laboratory support was provided by the Bureau of Biologics, the federal vaccine regulation agency, in suburban Washington, D.C.

A prime concern was that the vaccine itself might be contaminated or otherwise defective—a problem that could cause ill effects elsewhere in the nation and possibly force curtailment of the vaccination campaign. But the investigators, to their relief, were able to exonerate the vaccine on epidemiologic and laboratory evidence. The vaccine used for all three victims came from a single lot manufactured by Parke, Davis & Co. It was packaged in boxes, with 20 glass vials in a box, each vial containing enough vaccine for 50 injections. The vials were not opened until just before use. The circumstances suggested that, even if only a single vial of vaccine had somehow been contaminated—an unlikely occurrence in itself—many more individuals should have been affected than the three who died. Yet a telephone survey of more than 130 individuals who received shots at the same clinic that day turned up no adverse reactions other than a few sore arms. A survey of South Side hospitals found no other heart attack victims who had recently been vaccinated. And checks with health authorities in other areas where the same lot of vaccine had been used turned up nothing that seemed to implicate the vaccine. The clinching evidence was provided by the Bureau of Biologics—a battery of tests on all the empty vials used at the clinic that day, as well as on full, unopened vials, determined that the vaccine was properly constituted and contained no contaminants. "In short, there is no evidence to link the vaccine with the deaths," said Theodore Cooper, assistant secretary for health in the Department of Health, Education, and Welfare.

With the vaccine off the hook, the investigation focused on the South Side clinic itself. But once again, the investigators could find nothing irregular. The clinic was organized well, the nurses who administered the shots were competent, they used freshly opened vaccine and disposable syringes (the needle was deemed preferable to a jet gun for the elderly because it causes less pain and tissue damage to the arm), and the staff was well prepared for emergencies.

Coroner Wecht publicly suggested that the deaths might have been caused by a nurse inadvertently injecting the vaccine into a blood vessel—an allegation that angered the nurses to the point where some threatened to drop out of the campaign unless their honor was defended. But Wecht is speculating on rather skimpy evidence. He looked at a television film clip of shots being given at another clinic on another day and said it did not appear that the nurses, after jabbing the needle into the skin, were pulling back on the plunger to make certain they had not hit a blood vessel. If the plunger is pulled back and blood enters the syringe, the nurses are supposed to withdraw the needle and start over. If no blood is seen, they go ahead and inject the vaccine. Thus, if Wecht were right, it would mean the nurses could conceivably have hit a blood vessel without knowing it.

But federal and state health officials discount his theory on the grounds that competent nurses pull back the plunger by second nature, the maneuver is too subtle to be readily seen on film, there are no significant blood vessels in the deltoid muscle where the shots were administered, the needle was too short to penetrate deeply, and no one can think of a physiological mechanism that would cause death even if the vaccine were put directly into a vein. Such intravenous injections have been given to animals without causing fatalities. The nurses at the clinic rotated frequently to avoid fatigue, so investigators have not determined whether a single nurse inoculated all three individuals who died.

Other Hypotheses

Some observers have raised the possibility that the vaccine might have interacted with other medications taken by the three chronically ill victims in such a way as to cause their deaths. Federal epidemiologists say they have not examined this question exhaustively. But they know that the three victims were on medication that is commonly used by a lot of elderly people, including vast numbers who have been immunized with no ill effects. Moreover, investigators have difficulty imagining how the vaccine would interact with other medication on a pharmacological basis.

Wecht and others have also suggested that the vaccination campaign might have indirectly caused the three deaths by putting the victims under stress. In making this charge, they have unquestionably highlighted a weak point in the vaccination campaign here and probably elsewhere. A barrage of publicity urging the elderly to protect themselves against the swine flu menace and suggesting that there might not be enough vaccine to go around resulted in long lines at many clinics. Hundreds of senior citizens stood in the cold rain on opening day—a pathetic and ludicrous reminder that public health measures can become counterproductive. It was clearly a failure of planning and administration. But the failure does little to explain the three deaths. The coroner's own field investigator interviewed the relatives of the deceased and found there was no waiting line at the South Side clinic when the three victims arrived. Nor was it raining that day.

A variation on the stress theory is that the campaign, with its high-powered publicity, may be coaxing sick people to the clinics who should really stay home in bed. There is some evidence to support this. But there is conflicting information on whether the three individuals who died were abnormally ill before journeying to the clinic. A friend of one of the deceased told county health officials the victim left a sick bed to get vaccinated, but the family claims the victim was feeling fine. Neither federal nor county health officials have interviewed the relatives to ascertain the health of all three deceased on the day they got vaccinated.

The possibility that stress might be adversely affecting some individuals led the county health department to modify its procedures when the immunization campaign was finally resumed. One clinic was moved to a bigger facility, visiting hours at each clinic were staggered alphabetically in an effort to reduce lines, and plans were made to vaccinate more people in their usual environments rather than in central clinics. The most dramatic change was that all persons with chronic illness were urged to get vaccine through their private doctors. The rationale for this was that a personal physician would best know his patient's state of health, and a shot in the familiar doctor's office would be less stressful than in a crowded clinic. The changes seemed admirable. But whether such procedures would have prevented the three deaths remains conjectural. Clack, the veterinarian who directs the county health department, says the new procedures in no sense imply a belief that the three deaths were caused by stress at the clinic.

That leaves coincidence as the official explanation for the cluster of deaths. But there is sharp disagreement over how likely it is that three such deaths would occur normally. The disagreement stems

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primarily from different assumptions about the appropriate population base to be considered in estimating probabilities. This is a problem that traditionally frustrates cluster analysis. Does one ask how likely it is that three deaths would occur normally on a given day among the relative handful of people who were vaccinated during the critical hour at that one clinic, or among the 1200 who were vaccinated at the clinic that day, or among the 8000 or so elderly who were immunized in Allegheny County that day, or among even larger groups of elderly immunized in the state or nation?

Using one set of assumptions, the Center for Disease Control, which is promoting the immunization campaign, has managed to calculate the odds as low as 1 in 50 that the deaths would occur normally. Using another set, the county coroner's office, acting as devil's advocate, puts the odds as high as 1 in a million. One neutral expert—Robert J. Armstrong, chief of mortality statistics at the National Center for Health Statistics—has a gut feeling that the deaths were "an extremely rare event—a tremendous long shot." But he notes that highly improbable events do in fact occur.

Federal officials also stress that, on a nationwide basis, the death rate following vaccination is far less than the normal death rate for the elderly population, a statistic which tends to exonerate the vaccination campaign as a cause of mortality. But skeptics put little stock in such figures. They doubt that the reporting of deaths after vaccination is complete. They also suspect that most of those who are about to die on any given day are too sick to venture out for a flu shot. Thus the population that visits clinics might be expected to show fewer deaths.

One federal investigator who is skeptical that the three deaths were coincidental is Philip Graitcer, one of two specialists from the Center for Disease Control who masterminded the investigation here. Graitcer speculates that some of the deceased might have been killed by hysteria or stress at the shock of seeing others collapse, receive oxygen treatment, and then get carted away on a stretcher, amidst a wailing of sirens. He hopes to return to Pittsburgh soon to investigate this hypothesis more thoroughly. If his theory proves plausible, it might explain how the million-to-one shot occurred. It might also suggest the need for new procedures aimed at minimizing the hubbub caused by medical emergencies.—PHILIP M. BOFFEY

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depression led Friedman to invert the proposition—an essentially stable private sector operates as a shock absorber to the shocks imposed by an erratic and "unstable" government sector. This inversion created much intellectual heat. It is noteworthy, however, that Friedman provided us with the only piece of evidence we have on an issue of fundamental importance. The issue is anything but settled. But again, Friedman raised a radically unfashionable question and we should hope that scholarship will attend to its serious examination.

My presentation of Friedman's work to a wider group in the scientific establishment has concentrated on his extensive scholarly work. But the new Nobel Prize winner is far removed from "academia's ivory towers." He has been embroiled for many years in important issues of public policy. This aspect of Friedman's life deserves some clarification. He is frequently presented as an ideologue, as a man who lets his politics dominate his economics. He is also refered to patronizingly as a "controversial figure."

The accusation that politics plays an important role in Friedman's work thoroughly distorts the actual situation. The remarkable fact is that many of Friedman's "political or policy views" were guided by a strong commitment to a relevant empirical use of economic analysis. His "politics" emerges to a major extent as an assessable consequence of his economic analysis. Analysis led him to a series of quite radical questions bearing on many of our social institutions, or more specifically, on the prevalent views of stabilization policies. The proposal for a monetary rule was not motivated by any "laissez-faire preconception" but evolved from his appreciation of the unpredictable variability of monetary lags.

And, lastly, there is indeed a commitment. It involves the value and freedom of an individual human being, and a commitment to rational discourse and the cognitive adventure called science. But views about social institutions, their mode of working, and their consequences remain a matter subject to the procedures of empirical science. Perhaps we may hope that Friedman's lifelong struggle to insert such scientific commitment into economics may yield a broader application of relevant analysis over the full range of social institutions and political processes.

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less homogeneous and their teaching load very heavy. In contrast, others viewed a mix of both 2-year and 4-year college teachers in the same course as mutually beneficial.

There was some sentiment for courses specifically designed for academic deans and faculty development officers. One participant felt that several of the short courses would also benefit nonscience faculty, and another thought that the current program seems more profitable for nonscientists than scientists.

A potpourri of suggestions for the content of the short courses emerged:

- more emphasis on lab-centered and hardware-type courses, perhaps 1 or 2 weeks in duration;
- the latest laboratory techniques—what's going on at the leading laboratories in the country;
- courses on the current year's happenings in biology, chemistry, or physics; and
- more on improved methods of teaching the sciences, such as how to develop teaching materials; how to reach nonmajors; how to apply the techniques of modular instruction to the all-important introductory course.

A suggestion that the AAAS consider arranging some sort of credit for short courses highlights a basic question which was asked and discussed, but not resolved: How do you motivate faculty who are comfortably uninterested in self-improvement?

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Nuclear Power Seminar Scheduled

A regional seminar on nuclear power, cosponsored by the AAAS Division of Public Sector Programs and Knox College, will be held on 1 December on the Knox College campus in Galesburg, Illinois. The program will include a discussion of the Illinois energy picture, the nuclear fuel cycle, and a number of concerns associated with the safety and waste management of nuclear power.

AAAS members in the Galesburg area are invited to attend. For further information, contact Dr. Herbert Priestley, Knox College, Department of Physics, Galesburg, Illinois 61401. Telephone: (309) 343-0112, Ext. 248/485.