

PUBLIC HEALTH: PAST ADVENTURES and FUTURE EXPECTATIONS

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DA Henderson, MD, MPH, Distinguished Scholar
Center for Biosecurity, University of Pittsburgh Medical Center

I thank you for inviting me to this significant meeting and the opportunity to put in context the evolution of our concern regarding preparedness measures. None in the field of public health are more important than those of you on the front lines in our efforts to translate concepts into action. You constitute a unique professional group who are forever being asked to do twice as much as you have done in the past but with ever fewer resources. You certainly have my respect. You represent the heart of our national public health preparedness program — a critical component of our domestic national security.

It was with those in state and local health departments that I received my education as to the practical realities of public health. My education extended over an 11-year period beginning in 1955. I began as one of the first of Alex Langmuir's EIS officers — shoe-leather epidemiologists, as we were called (in contradistinction to the shiny pants epidemiologists but I will stop there). And for 6 years I served as Chief of the CDC Surveillance Section. There were few of us then at CDC and with no cell phones, no fax, no internet, no Facebook. It seemed to me that we were almost constantly in the field or on the telephone. And those in the state and local health departments taught me a lot.

It was an exciting time. During those years, oral polio and measles vaccines were licensed and special programs for immunization were launched — some will remember the *Sabin on Sunday* city campaigns when efforts were made to vaccinate all children in a city on one day. But another historical side note — In 1960, CDC assumed responsibility for publishing the Morbidity and Mortality Weekly Report and I became *de facto* its first editor. It started as nothing more than a dull compilation of numbers, including a weekly count of deaths in 109 cities. I proposed that we drop that table but there was an unexpected wave of protests from undertakers and funeral directors. This publication was their business index. They followed it weekly to measure their success in garnering a share of the market. Of the 5000 copies of the MMWR produced each week, 4000 went to this group. That changed as we began to document current outbreaks and investigations. Circulation went up and the MMWR became a principal medium for communication regarding current public health issues. However, the undertakers continued to subscribe.

This morning, let me endeavor to offer a personal perspective about the changing dimensions of activities now grouped under the rubric of public health preparedness — a

subject which is a priority component of our systems providing national security. I do this advisedly because many have forgotten how the initiative arose and why.

NEW AND EMERGING INFECTIONS

From the early 1950s, interest in infectious diseases gradually waned as ever more antibiotics and vaccines became available. Complacency about infectious diseases pervaded to the extent that Nobelist MacFarland Burnett proclaimed that an era had passed — the infectious diseases had effectively been conquered.

However, interest reawakened in 1982. A new disease, AIDS, was discovered and the causative HIV virus was isolated. Optimism that a vaccine would be discovered soon vanished, but fear did not. How contagious it might be was uncertain. Those who were in advanced stages of the disease were immuno-compromised and manifested all manner of secondary infections. It was a hideous disease and those staffing hospital wards did so with trepidation, fearing that they might acquire it.

It soon became apparent that AIDS had originated somewhere in Africa. Serious questions arose as to whether there might not be other agents, equally as deadly and perhaps more rapidly transmitted. In 1989, at one of the first meetings of those concerned with the possible threat of other as-yet-unknown microbes, Dr. Josh Lederberg, a Nobel Laureate, posed the question: Is it conceivable that a virulent new virus might emerge that has a very long incubation period (like AIDS) but that is highly contagious? By the time the disease was discovered and diagnosed, it might be almost too late to devise drugs or vaccines to deal with it. There was a long, solemn silence. One of the virologists present quietly replied: “It has to be accepted that this could happen.”

I had personally not thought of the problem in these terms. I couldn't stop thinking about it. Increased emphasis began to be placed on the early identification of other new or emerging microbes with hopes that, if found early, control measures might be invoked in time to counter them. And, indeed, we have been rewarded with a number of surprises — SARS, West Nile virus, Ebola virus, and 3 new influenza pandemic strains, to note but a few — in just 50 years. There will be others. Mother Nature has her own capacity to produce biological pathogens and we cannot forget this.

Efforts are now being made to improve disease surveillance in all countries. Some success has been achieved in learning to produce new vaccines and antimicrobials more rapidly. Overall, however, support for these efforts has been modest. Progress and interest have waned after the first spasms of anxiety regarding such as HIV and then SARS. Indeed, complacency about the threat of new and emerging infections waned steadily again until one more event dramatized the fact that preparedness took planning, resources, and time that could not be ordered up for fast shipment from Amazon.com.

In 2004, H5N1 bird influenza appeared in southeast Asia. The virus had been first identified eight years earlier in Hong Kong. In that outbreak of 18 cases, 6 persons died. City authorities took heroic measures to stop the spread and for a while it appeared to have vanished. But it reappeared, spreading rapidly among chickens; it could wipe out an entire flock within a few days. More than 500 human-contact cases have occurred, and half of them died. Fortunately, the disease seldom spread from person to-person. But the danger that it might mutate and spread more readily among humans was an ever-present possibility. Hundreds of millions of dollars have been provided to expand influenza vaccine manufacturing capability; surveillance has been strengthened; and laboratory research intensified.

In November, two different laboratories reported having created mutants of the virus that are readily transmitted from one experimental animal to another. They point out that nature itself might develop such a mutant. Imagine the scenario of a rapidly spreading influenza virus with a capacity to kill even 10% to 20% of its victims and in one year to spread around the globe. Note that the 1918 influenza, as bad as it was, killed only 2%. In the US, 500,000 died. Were the new strain to begin to spread among humans, fatalities could number 20 million or more in the US alone. Do we now know how to stop it? No. Could ample vaccine be prepared rapidly enough to thwart its spread? No. The scenario is still evolving. Infectious diseases are still with us and still a world-class problem.

MICROBES AS A BIOTERRORIST WEAPON

An unexpected naturally-occurring epidemic threat of a new microbe is ample justification for public health preparedness, but there is a second threat, one that is equally as ominous — a microbe used as a bioterrorist weapon. That organisms could be used as effective weapons has been recognized for nearly a century. However, this possibility had been generally dismissed as too morally reprehensible to deserve attention. That changed dramatically after September 11, 2001, and the anthrax attack that followed. The attacks on the Trade Towers and Pentagon were appalling but there was more to come.

As an aside to the flow of events: On the Sunday afternoon following the attack, I received a call from DHHS Secretary Tommy Thompson. I had never met him. He asked that I come to a meeting at 7:00. I asked whether he meant Monday morning or Monday evening. He said, "Tonight". I drove immediately to Washington and met with Secretary Thompson and senior staff until midnight. He had just received information that intelligence intercepts indicated there would be a second "event", almost certainly biological, most likely smallpox or anthrax. We were desperately unprepared.

SOURCE OF CONCERN ABOUT BIOLOGICAL WEAPONS

Who might be the perpetrators of an attack? Since World War II, it had been recognized that, if microbes were used as weapons, the results could be catastrophic. In 1972, President Nixon led in engineering a treaty, signed by all nations, that required all to stop work on biological weapons and to destroy what stocks they had. No provisions were made for inspections to verify this. Nixon was not concerned, however. He said that if a country attacked us, we would simply “nuke ‘em”.

Subsequent to 1972 and extending into the 1990s, biological weapons were considered by the scientific community to be morally reprehensible. After all, the Biological and Toxin Weapons Convention had been signed by all countries. The most feared of the agents — smallpox virus — was locked up in two laboratories. No consideration was given to developing preparedness programs. No one had assigned responsibility for biological weapons at either CDC or NIH.

Twenty years ago, the first tremors that began to shake this tranquil scene. In 1992, the deputy director of the Soviet bioweapons program defected. He revealed that there were 60,000 workers in 50 different laboratories conducting research on new and improved biological weapons. Their three top-priority agents were smallpox, anthrax, and plague. Initially, few believed him, but other defectors and additional information confirmed it. And, as we were to learn, there was a large manufacturing plant north of Moscow capable of producing annually upwards of 20 tons of smallpox virus.

The threat posed by the Russian reservoir of expertise was soon compounded. With the collapse of the Soviet Union, many research scientists from the laboratories fled to other countries — including the U.S., Europe, and Asia, carrying with them skills for making biological weapons agents and perhaps taking vials of the agents as well. Little is known as to where most of them went. And we know next to nothing about the possible extent of current activities in rogue nations. Detecting possible biological weapons production facilities is difficult to impossible. A few personnel with little training and modest resources can produce large quantities of usable microbes.

PRE-2001 MOUNTING A BIOPREPAREDNESS PROGRAM

Fear of possible terrorist attacks persuaded President Clinton of the need to strengthen our preparedness activities in the interests of national security. Thus in 1995, federal support was provided to the Defense Department for establishing and training first-responder teams in major cities. The teams were comprised of police, fire, and emergency rescue personnel. No provision was made for medical or public health personnel. I was deeply concerned.

Public health had to be a critical component of a preparedness program. There was a need to educate both the Executive Office and Congress of this, but who could do it?

The mere subject of preparedness to deal with biological weapons was considered to be morally repugnant by schools of medicine and public health. There was little interest or expertise in the Department of Health and Human Services (DHHS). A special center could be a starting point and so I sought help in developing such a center from several foundations. All declined. Each expressed interest but insisted that its trustees would not look favorably on a foundation being engaged in any activity that dealt with biological weapons.

A desperate final visit to the Sloan Foundation, however, brought an offer to fund what was needed. Thus, what is now the Center for Biosecurity came into existence in 1998. Drs. Tara O'Toole and Tom Inglesby joined me in a new venture to persuade the government that a national preparedness program was needed. One of our first initiatives was to convene a group representing federal, state, and local interests to assess a course of action. The group identified six agents as being those of greatest concern (the Group A list). There was then no manual nor papers describing the current recommended practices for the medical and public health management of outbreaks involving these agents. With leadership from the Center, experts developed consensus papers. These were published in JAMA and later became a standard manual.

Countless meetings followed at medical centers, Congress, and professional meetings. In 1999, the first steps in civilian bio-preparedness were taken when an Assistant Secretary for Preparedness was appointed and funds allocated. The support was modest — \$150 million — of which \$80 million was for the states for epidemiological and laboratory support, electronic communication, and augmentation of CDC's response capability. The resources were modest indeed considering that this had to cover 50 states, more than 100 major cities and 3,000 counties.

RESPONSE AFTER SEPTEMBER 11

As preparations began, smallpox was considered to be our greatest concern. The disease kills 30% of its victims. There is no therapy. Vaccination had stopped 30 years previously; probably 75% of the U.S. population was susceptible, as were others throughout the world. Without adequate vaccine, epidemics could not be stopped. But the US had little vaccine. After vaccination ceased in 1980, vaccine manufacturers destroyed their production facilities. As of September 2011, there were only 15 million doses in the US. But it had been kept in -20°C. storage and almost certainly could be diluted 1:5. A call was made to CDC to inquire how much vaccine could be immediately dispatched if necessary. The answer was 90,000 doses. The diluent had deteriorated and the vaccine had not been regularly titred for potency

The status of preparedness at state levels was not better. We surveyed state officials to obtain the state 24/7 emergency contact telephone numbers. We discovered that 12 had no emergency contact number; 8 knew they had such a number but couldn't remember

what it was. We made a Saturday evening call to CDC to ask to talk with someone about an acutely ill patient with high fever and funny pustular lesions on the body. The guard who answered wanted to know what the disease was and insisted he couldn't refer the call without knowing the name of the disease.

State and city laboratories were hopelessly under-funded. At the time, only two laboratories had the reagents and capability to diagnose smallpox. Perhaps 4 or 5 could diagnose anthrax.

But then, on October 4, a case of anthrax from Boca Raton Florida was reported. Soon thereafter, there were other reports from New York. It became clear that anthrax spores had been sent in letters and that cases had occurred in senatorial offices, television broadcast studios, and workers in postal sorting rooms. CDC mobilized large numbers of epidemiologists, but it was a chaotic scene. Information flowed in from many different sources, making it difficult to discern the likely magnitude of the outbreaks and to determine what agencies and investigators were finding. As it eventually turned out, there were only 22 cases.

Meanwhile, teams of first responders in some cities acted according to their training — they washed down presumably exposed persons as one would after a chemical attack. No one seemed to want to contradict the advice. Unhappy wet office workers, some in their underwear, in parking lots adjacent to office buildings, made for dramatic press. Laboratories were deluged with specimens of white powder — many from powdered doughnuts. No priority guidance was provided as to what were key specimens. Most laboratories were not equipped, in any case, to undertake the needed diagnostic tests. Hand-held sensors that supposedly could identify anthrax spores began to surface. They had been provided to first responders in training courses and were liberally used by them in the field to determine which powder specimens contained spores and which did not. We finally had to explain that a more accurate instrument was a simple coin — heads, it was anthrax; tails, it was not. Questions were eventually raised about decontamination and its end point. The only advice was “zero spores”, a patently ridiculous standard but better advice has yet to be offered.

There could not have been a better illustration of how unprepared the country was for this or any other bioterrorist event.

On January 9, the President signed an emergency authorization providing \$3 billion to DHHS for emergency preparedness. There was considerable discretion in how this was to be allocated. At the time, I argued the case for one-third of this to go to states and local health departments. In dealing with epidemics, whether in this country or elsewhere in the world, it was all too apparent that success in controlling disease outbreaks depended heavily on local leaders and local organizations whatever their nature. One could parachute in any number of foreign workers and experts, whether civilian or

military, and fail miserably in the absence of community support and cooperation and some sort of defined structure.

Accordingly, one billion dollars was assigned for distribution through the states for use in city and county jurisdictions as well. Broad guidance as to generally indicative mileposts and relevant areas (such as surveillance, laboratory, community organization, training) for which it was intended. Knowing that all states differed in their needs and strengths, we left it to the states to determine how best to distribute the funds. Within weeks plans had been submitted by most states. We were impressed by the thoughtful and creative plans submitted by most. We recognized that much more in the way of resources would be needed if we were to have a structure that truly provided the major domestic component of NATIONAL SECURITY — a continuing national priority concern. Meanwhile, a special hospital preparedness program was funded that we had expected to be essentially a part of the package of funds being made available for community development. Hospital preparedness must be a totally integral activity with community preparedness planning. For bizarre administrative reasons they were separated and so the two went their own separate ways with little coordination.

WHERE ARE WE NOW?

In our earliest discussions at the Center, we really wondered whether it would be possible, in today's complex and specialized environment, to bring together the many often fiercely independent groups and organizations to undertake joint community planning and implementation efforts. In many areas, hospitals, private physicians, and public health professionals seem to exist on different planets. How could others—such as the Red Cross and other non-governmental organizations, private-sector business, and clubs such as Rotary, Lions and others—effectively blend in? On the surface, it would seem that such a concept was idealistic and impractical. Certainly it would take time to evolve.

In fact, whatever the reasons—fear of an epidemic or a recognition that the world is changing—we have been surprised by the extent of many remarkable developments in many parts of the country. There are a substantial number of different cooperative public health enterprises and joint planning exercises including volunteer groups, enhanced IT communications, coordinated central command centers, and others. Dr. Ali Khan, now Director of CDC's Office of Public Health Preparedness and Response, summarized many of these well in a September issue of *Lancet*.

However, there is an inexplicable dark side. (*SLIDE HERE — A COMPLACENCY CURVE*) I have had occasion just within the past two weeks to talk candidly with several in state and city leadership positions and to study public health preparedness budgets. I cannot believe what I am seeing and hearing. Funding is obviously critical for further developing and sustaining the program. Lo and behold, contrary to all logic, the budget

for preparedness, instead of steadily increasing, has been progressively cut and cut severely. The problem is now compounded by other decreases in state and county funds. At the beginning, we allocated one billion federal dollars for public health preparedness and response programs at state and local levels. It was widely recognized as being a vital part of our domestic National Security Program. We fully expected that this would increase as the new programs became established and we could better determine the greater needs. Quite to the contrary, I now find that the allocations have eroded to the point that they are 40% less than what they were; the hospital program has fared no better. I am especially puzzled because other components of our national security system have been sustained or are growing.

The implications in real terms are even more discouraging as I talk with state and city leadership. The majority of the decreases are reflected in cuts in personnel. These include:

- Significant numbers of now experienced and community-connected epidemiologists in leadership positions for disease investigation and needed organization for disease control, including vaccination
- Experienced laboratory staff with consequent closure of a number of laboratories
- Staff engaged in training of volunteers and community personnel

Within the past 14 days, I have had personal direct discussions with several state and community leaders. Who of the state leaders and one responsible for a metropolitan program spontaneously offered the view that their programs had been so severely constrained that they were close to being non-functional. Further cuts in FY2013 would possibly complete the task.

Development of an effective preparedness program requires years to evolve and mature. Cut significantly, it can be effectively destroyed within a matter of a year or less.

The major impetus for this program grew from the recognition that the country could be challenged by far larger problems conceived either by Mother Nature or by terrorists. Why the steady erosion of support for a program that is at the heart of our National Security efforts while components in other departments are continuing or increasing their budget allocations?

I can fathom only one explanation for this — COMPLACENCY. It took the anthrax disaster to capture the attention of policy makers. Must we now have another truly catastrophic epidemic disaster before there is understanding? I'm afraid it is inevitable based on the record of the past 10 years.

Center for Biosecurity

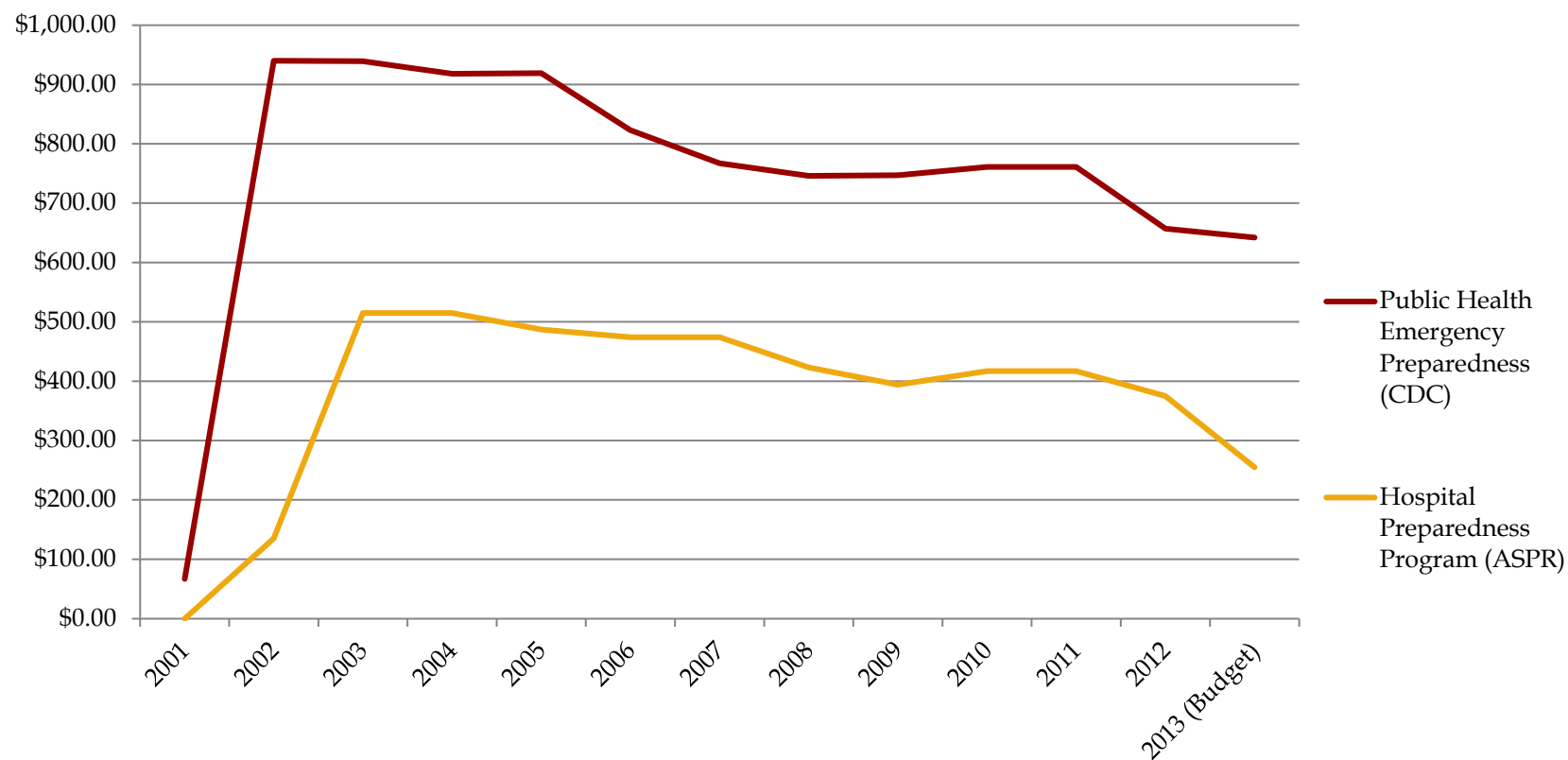
Public Health:

Past Adventures and Future Expectations

D.A. Henderson Distinguished Scholar

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A COMPLACENCY CURVE



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