DISEASE SURVEILLANCE SYSTEMS

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HOW CAN THEY HELP US PREPARE FOR BIOTERRORISM?

WEDNESDAY, SEPTEMBER 24, 2003

U.S. HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON EMERGENCY
PREPAREDNESS AND RESPONSE,
SELECT COMMITTEE ON HOMELAND SECURITY,
Washington, DC.

The subcommittee met, pursuant to call, at 2:54 p.m., in Room 2318, Rayburn House Office Building, Hon. John Shadegg [chairman of the subcommittee] presiding.

Present: Representatives Shadegg, Shays, Diaz–Balart, Thornberry, Gibbons, Thompson, Norton, Christensen, Etheridge, Lucas of Kentucky, Cox, Turner and Dunn.

Mr. SHADEGG. [Presiding.] The committee will come to order. I would like to welcome our panel. I apologize for the slight delay in starting. As you know, we had a series of votes on the floor. I am certain there will be members trickling in over the next few minutes.

Today, we will be examining the role of disease surveillance systems in preparing our nation for bioterrorism. Clearly, the most preventive action we can take in terms of bioterrorism prevention and preparedness is to develop countermeasures against them so that even if terrorists strike, their intentions would be thwarted because the American public would be immune.

The committee and the House took a critically important step by passing Project Bioshield, an effort to stimulate investment in bioterror countermeasures. I am pleased that funding for that important program was approved as a part of the homeland security appropriations conference report passed just earlier today.

While we wait for the innovation of biotech, pharmaceutical and medical device companies to develop those countermeasures, however, the second most preventive thing we can do is to be looking at ways in which to be able to detect a potential outbreak through either surveillance systems or monitors so that we can take proactive steps to stem its spread. That is the focus of our hearing today.

Whether terrorists choose to spread a pathogen through the air, through our food supply or through our water supply, although sensors are being developed and tested, we likely would not know that such an attack had occurred until many citizens showed symptoms of that disease or that sickness. But how would we know that these symptoms are more than just an outbreak of the flu or a series of colds? How would we know, indeed, that patient symptoms were

the result of a release of a bioterror agent? Would our primary care and emergency department physicians, the so-called "canaries in the coal mine," be able to decipher the difference? Or would we have to wait for additional investigation by health plans and insurers to take place before we were able to recognize a pattern of sickness as in fact a bioterror attack?

Today, our expert panel will help us answer these questions and walk us through how disease surveillance systems work and what can be done to improve them and our nation's ability to detect bioterror attacks. With passage of the Bioterrorism Act of 2002 and subsequent appropriations, Congress has invested over $2 billion in bioterrorism preparedness and response. The bulk of that money has gone to the Center for Disease Control which spent over $1 billion upgrading public health laboratory capacity. Some of this money was spent to update and modernize many State and public health labs and computer equipment for improved communications ability. The CDC has been working to establish several information surveillance systems to move disease reporting from a paper-based system to one that capitalizes on new technologies. We hope to learn what sort of real-time analysis capabilities exist within our system today.

Again, in the fiscal year scheduled to start next week, we will likely invest close to another $1 billion in bioterrorism preparedness grants. As members of this committee have discovered over the past 6 months, communication is critical in our ability to successfully secure the homeland. For these disease surveillance systems to work, people must be willing and able to communicate. Healthcare professionals will have to be able to share information because CDC's ability to connect the dots is largely dependent upon the quality and the quantity of the information that is collected.

Last, what is the role of technology? How can we capitalize on America's ingenuity and our unparalleled advances in health research? I hope that Dr. Trent from own State of Arizona will be able to shed some light on this important aspect, given his experience serving as direct of the National Human Genome Research Institute at the NIH, and his current experience working on pathogen diagnostics at the Translational Genomics Research Institute.

I am pleased to have the panel with us today. By agreement, we have agreed to limit the opening statements to the Chairman and the Ranking Member of both the subcommittee and the full committee. I will now turn to the Ranking Member of the subcommittee, Mr. Thompson, for his opening statement.

Mr. THOMPSON. Thank you, Mr. Chairman.

Almost 2 years ago, the Congress faced head-on the impacts of bioterrorism when both the Senate and House were infected with a weaponized strain of anthrax sent through the U.S. mail system. The lives that were lost as a result of this terrorist attack were a terrible tragedy, and we must never forget our experiences during the response to that attack. It is critical that Congress and the Administration work to ensure that in the event of future bio-attacks we do everything within our power to prevent the loss of life and to identify those responsible for those unconscionable acts of terrorism.

Therefore I am pleased to have the distinguished witnesses with us to describe the role of disease surveillance systems in our preparedness for and in response to acts of bioterrorism. I am very interested in the testimony we will hear today and I hope that our witnesses would discuss both the recent advances in disease surveillance systems and perhaps more important, the need for additional resources or focus on the issue in order to ensure that we are fully prepared for the next bioterrorism incident.

As we will hear from our witnesses today, the Center for Disease Control and Prevention, RCDC, manages a complex national network of surveillance systems designed to monitor the emergence of certain diseases such as the flu. However, I remain concerned about the capabilities of our disease surveillance system because they represent the first line of defense to responding to acts of bioterrorism. These systems will provide us with the first indication that there is a problem, and will guide our response to that incident. A robust surveillance system will also allow us to quickly get vital information out to the public health providers and the public at large about a disease outbreak, and will help prevent the further spread of disease.

When a person becomes ill, he or she most often seeks treatment from a primary care physician. However, there are significant communication disconnects between individual doctors and the public health community in reporting diseases. If surveillance is to work effectively, doctors must report timely and accurate diagnoses in a standardized manner. In 2000, the Institute of Medicine convened workshops to follow their report emphasizing this point. For example, even when individual doctors are required by law to report certain diseases such as flu, they are, according to the Institute, notoriously lax in reporting such information to the public health authorities. One of the issues I will ask later is, when they are lax, what do we do? Slap them on the wrist, or just say better luck next time?

We must move faster, Mr. Chairman, and we must be stronger in our efforts to protect and defend the United States of America against acts of bioterrorism. I hope the testimony we hear today will assist us in developing a roadmap for doing so.

Mr. SHADEGG. Thank you.

I call upon the Chairman of the full committee, Chris Cox, for his opening statement. Chairman Cox?

Mr. COX. Thank you, Mr. Chairman. I want to thank you for assembling a fine panel to assist us today in considering how disease surveillance system can be of better use in the war on terror.

We know from several commissioned studies that we had information prior to 9–11 that, had we only pieced it together differently, might have permitted us, if not to learn of the terrorist plot before it was executed, at least to interrupt it. We might have taken enough of the individuals who were involved in it out of commission so that 9–11 might not have happened. Our government and the American people possessed information that they just did not put together because we were not thinking about this problem in this way.

We have I think the same problem presented to us today. Happily, the United States has not been hit with a bioterror attack on

the scale that we saw on September 11, but I have to forecast that were such an attack to occur today, we have commissioned reports on its aftermath that would tell us that we did not piece together the information that we had in the early moments of that crisis that would have permitted us to respond to it and prevent it from causing the damage that ultimately it would carry out.

We can learn, and this committee will learn when we have a complete report on Top–Off 2 from exercises. We know that our emergency room physicians are going to be heavily involved in the early stages of response. We also know that our emergency rooms are very overcrowded. They are going to be especially overcrowded when people are all coming at a time of crisis. We have to consider how the emergency rooms not only are going to put information into this system so it can be analyzed and dispersed across the nation rapidly, but also how they are going to respond if called upon to do so.

At least some of the testimony that we will hear today is going to ask us to take a look at the role of primary care physicians. The truth is that we have not been accustomed to thinking of primary care physicians as first responders in the same fashion that we have the ER physicians, but we know from Top–Off 2 and we know from the fact that our emergency rooms are overcrowded that they will be. As a matter of fact, they will be in the first line of casualties if they are not properly inoculated. This, too, is something that we have got to take a look at.

What we will learn today from the testimony that our witnesses have already provided to us, and even more so from the interaction during questioning, is that there is a lot that we can do with data collection and dispersal and analysis. There is also a question then that will remain for our committee, and that is what exactly should be the role of the Department of Homeland Security in taking advantage of these good ideas and carrying them into effect.

So I want to congratulate you, Mr. Chairman, for placing a focus on bioterrorism before it happens in this committee, and for assembling this panel of expert witnesses.

Thank you, Mr. Chairman. I yield back.

PREPARED OPENING STATEMENT OF THE HONORABLE CHRISTOPHER COX, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA, AND CHAIRMAN, SELECT COMMITTEE ON HOMELAND COMMUNITY

I would like to thank Chairman Shadegg and ranking member Thompson for their leadership in organizing today's hearing and recognizing the enormity of the bioterror threat. Many of us gathered here today witnessed first hand the effects ofbioterrorism in the fall of 2001, when Congress became a target of a biological attack. However, we are fortunate that only about 22 people were exposed to *Bacillus anthracis,* and as tragic as' any death is, that no more than 5 people died. One of the lessons that we learned from that event was that bioterrorism does not need a large body count to terrify our citizens, damage our economy, and threaten our democracy. Any terrorist with minimum technical sophistication and with some basic microbiology tools can accomplish the goal of bioterror- to inflict enormous social and economic disruption.

The recent SARS outbreak has taught us that natural emerging and reemerging diseases can cause widespread economic losses, devastating death tolls, and a heavy strain on the public health infrastructure. This outbreak provides a window into the damage that can be done by a″thinking″ enemy using a biological weapon with a deliberate plan to harm our citizens.

It should be noted that of the almost 8,500 SARS cases world wide and almost 800 deaths, the US reported no deaths during this outbreak. This is a direct credit to our front line clinicians, public healthcare workers and the leadership of Secretary Thompson in providing nearly $1 billion dollars from the Department of Health and Human Service over the past year for States and localities to develop bioterrorism response capabilities.

The members of this Committee, just last Spring, worked in a strong bipartisan manner to pass the President's BioShield legislation. This legislation not only provides for DHS and HHS to collaborate to provide countermeasures for potential biological weapons, but it also incentivizes the private sector to leverage its superior technology to produce vaccines and other countermeasures to help protect our citizens. Already, our focus in this area is paying dividends; recently we learned of a breakthrough in developing a vaccine against Ebola, a virus for which there is no other treatment. As a nation, we are making concrete strides in developing countermeasures and the technology to better prepare ourselves for a potential bioterror attack.

Our best defense, of course, is early detection. The sooner we have the capability to detect a bioterror attack, the more time we will have to intervene and lessen the effects on our society. I look forward to the testimony that each of you will offer in the area of early diagnosis and the status of public health systems, which will screen for trends in large numbers of patients. Early recognition is crucial to curbing the spread of a bioterror attack and administering treatments.

The dedication that each of you have shown in this area not only enhances our capability to respond effectively to a bioterror event but strengthens our healthcare infrastructure and the capacity to deal with natural epidemics.

Mr. SHADEGG. I thank the gentleman for his opening statement. I now call upon the Ranking Member of the full committee, the gentleman from Texas, Mr. Turner.

Mr. TURNER. Thank you, Mr. Chairman.

I appreciate our distinguished panel being with us today. In my view, the threat of biological attack is perhaps the most troubling, the most disturbing, potentially most catastrophic event that could ever occur as a result from terrorism. I am also firmly of the opinion that as we try to deal with the threat of terrorism, that we have to look further ahead into the future and anticipate what our terrorist enemies may try to do and have the capability to do in the future, than we are today.

For that reason, I commend the Chairman for his foresight in holding this hearing. There is no doubt that if we are going to plan to deal with bioterrorism, we have to start working on it now.

I also believe that when we look at bioterrorism, we know that we probably have a greater need to make a commitment of financial resources today than in any other area in terms of the terrorist threat. When we reviewed our legislation that this Committee dealt with just a few weeks ago, Project Bioshield, we were acutely aware that that legislation dealt with the tail-end of the vaccine production inresponse to a bioterrorist attack. What I think we need to be doing a better job of is dealing with the front end—dealing with the development of detection capabilities and developing the response capacities to biological pathogens that our terrorist enemies may be able to produce.

There is no question that trying to defeat bioterrorism up front is very difficult, because it can all be done within the confines of a small lab and spread by humans who may travel into our country by air or other method, and simply walk around among our populace, infecting literally tens of thousands of people in a very short period of time. So this is a threat that we must take very seriously. I am very pleased that our panel is here today to help us with this most important challenge. I am confident that with your help, we

can bring the right amount of public and congressional attention to this issue to allow us to begin to move forward on an issue that we must address now. It not only deals with our survival, but perhaps the survival of the entire world.

So thank you, Mr. Chairman, for calling this hearing today.

Mr. SHADEGG. I thank the gentleman for his opening remarks.

Without objection, the opening statements of all members will be included in the record. In that regard, I would ask unanimous consent to enter the opening statement of our colleague Mr. Gibbons who could not be with us here today. Without objection, so ordered.

I also ask unanimous consent that Mrs. Dunn, the Vice Chairman of the full committee, be allowed to sit and ask questions at today's hearings. Without objection, so ordered.

Now, to address the topic of disease surveillance systems and how they can help us prepared for bioterrorism, it is my privilege to welcome and introduce our distinguished panel. First, we have Joseph Henderson, associate director of terrorism preparedness and response at the Centers for Disease Control. Thank you for being here. Next is Janet Heinrich, pubic health specialist at the General Accounting Office; Dr. Richard Platt, chair of the Ambulatory Care and Prevention Department at Harvard Medical School and Harvard Pilgrim Health Plan. Thank you for being here. Dr. Jonathan Temte, infectious disease specialist with the American Academy of Family Physicians and associate professor at the University of Wisconsin; Dr. Jeffrey Trent, president and scientific director of T–Gen, the Translational Genomics Research Institute.

Ladies and gentlemen, we appreciate your being here today. At this point, we would appreciate your opening statements. We will not hold you strictly to 5 minutes, but hope that you will endeavor to stay somewhere close to that time limit.

[The statement of Mr. Gibbons follows:]

PREPARED STATEMENT OF THE HON. JIM GIBBONS

Mr. Chairman, thank you for your leadership and the insight to establish a panel with such knowledge on this critically important issue. I welcome the members of the panel and look forward to the information they will provide on the best proactive techniques and measures available to improve homeland security.

Different from biologic warfare which attempts to kill, bioterrorism thrives on public fear, potentially immobilizing or demoralizing a population. Countering such fears are public knowledge, and purposeful scientific and political pre-event action.

In the years since the attacks on the World Trade Center and the Pentagon, in big cities and in small towns, on bridges and at border crossings, Americans have been mustering resources in preparation for an assault from the shadows, recalculating the realm of possibilities.

In a sense, the effort to shore up the home front against terrorism is an exercise in seeking balance: between added security and reduced openness and convenience; between the likelihood a threat might materialize and the cost of eliminating it..

Bioterrorism involves the intentional or threatened uses of viruses, bacteria, fungi, toxins from living organisms, or chemicals, to produce death or disease in humans, animals, or plants. Many biological agents could be used to make weapons, however most experts agree that only a limited number of well-known biological agents would cause widespread illness and death.

As I understand the process, an announced event will be evaluated at the time by primary health care providers, public health and law enforcement. An unannounced event will be detected by private health care providers, infection control and/or public health surveillance as an unusual disease or death occurrence, once the disease starts to manifest itself in the victims. Prompt recognition and reporting is important to prevent spread and control future cases.

The Question we seek answers to today: How do best identify a bioterrorist attack and minimize the post-action effects?

Again, I welcome our witnesses and look forward to their keen perceptions on the latest disease surveillance systems.

Mr. SHADEGG. We will begin with you, Mr. Henderson.

STATEMENT OF MR. JOSEPH HENDERSON, ASSOCIATE DIRECTOR FOR TERRORISM PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL

Mr. HENDERSON. Good afternoon, Mr. Chairman and members of the subcommittee. I am Joseph Henderson, director of the Office of Terrorism Preparedness and Emergency Response at the Centers for Disease Control and Prevention. I am accompanied by Dr. John Loonsk who is CDC's associate director for informatics.

Thank you for this opportunity to discuss how disease surveillance systems can help to detect a potential terrorist attack. Disease surveillance systems or disease detection systems address one important aspect of our nation's overall public health preparedness strategy. The CDC, working with our Federal, State and local partners, is working to build systems that can rapidly detect an outbreak or an attack in our communities, mobilize the appropriate response to contain the event, and assure that our affected communities return to a sense of normalcy following the attack.

As requested by the subcommittee, I will focus on the rapid detection component of this overall preparedness system. Surveillance for diseases in the population is best described as the ongoing identification, reporting, collection, analysis and dissemination of critical public health data. These data inform public health officials of disease in their communities, enabling them to intervene, leading to control and containment of the disease. Without these systems, intervention would be significantly delayed, having much higher impact by way of increased illness, injury and in some cases death.

Recent events such as SARS and monkeypox have underscored the essential role early detection systems play in mobilizing rapid response. Detection of a disease almost always occurs at the local level where healthcare professionals and encounter patients seeking medical assessment or treatment. A clinician's ability to quickly recognize and identify symptoms of unusual illnesses on the frontline has been critical to CDC's ability to recognize unfolding disease events and implement containment measures.

Today, I will address three critical components of our disease detection systems: our current state of national disease detection capability; the public health information network which is our IT framework to enable and amplify detection and reporting capacities; and I will provide a brief glimpse of our global disease detection initiatives. I will try to do this within 5 minutes.

The most vital link in our current disease detection and reporting chain is the trained and astute clinician who would be the first to assess and diagnose individuals who are ill requiring care and treatment. CDC has been working with our State and local public health agencies, school and universities and numerous professional organizations across the country to educate our nation's health protectors. Frontline workers armed with the appropriate knowledge and information allows for rapid disease detection in our commu-

nities, whether naturally occurring or intentional, such as an act of terrorism. Clinicians and laboratorians report diseases to State and local agencies, in many cases required by law, which in turn share information with the CDC. The CDC and our State and local public health colleagues define conditions that should be reported and develop and disseminate guidelines to healthcare providers, infection control practitioners, emergency department physicians, laboratorians, and other members of the healthcare system to enable effective reporting.

However, improvements are necessary to do this work faster and with a higher degree of accuracy. Many local reporters of disease still report to public health agencies via fax. Reporting systems are largely paper-based and burdensome to all levels of the reporting effort. A comprehensive surveillance system requires a strong foundation at all levels of local, State and Federal public health agencies. Since September 11, 2001, the Administration had budgeted for and Congress has approved over $2 billion to develop and sustain State and local public health readiness, specifically to enhance capacities to detect, respond, contain and recover from biological, chemical and radiological acts of terrorism and other public health emergencies. States are spending significant portions of these funds to enhance epidemiological and event detection capacities and to develop and leverage information technology and systems to support various public health functions. A number of examples of these efforts can be found in my written statement.

For many years, CDC has supported the development and implementation of information technology systems for State and local health agencies to improve the practice of public health. Many of these systems operate in isolation, not capitalizing on the potential for cross-fertilization of data exchange. A cross-cutting and unifying framework is needed to better integrate these data systems to support early detection of public health conditions and emergencies. The Public Health Information Network, or PHIN, provides this framework. The PHIN will enable consistent collection and exchange of response, health and disease tracking data among public health partners.

PHIN encompasses four components: detection and monitoring; analysis and interpretation; information dissemination and knowledge management; and public health response, which is described here on this poster. I will briefly describe each of these particular components.

Detection and monitoring. The CDC is in the proof of concept stage for a project called BioSense, which proposes early event detection associated with a possible bioterrorist threat. BioSense could establish the capability for rapid, around-the-clock electronic transmission of data to local, State and Federal public health agencies from national, regional and local health data sources such as clinical laboratories, hospital systems, health plans, the Department of Defense, VA medical treatment facilities, and pharmaceutical chains.

This proposal is based on utilizing existing data and information so as not to add to existing reporting burdens. The National Electronic Disease Surveillance System, or NEDSS, is another system that falls under the PHIN framework, supporting the development

of real-time reporting of information for public health action. NEDSS requires adherence to standards-based approaches such as Federal e-government standards to ensure data and information are collected and disseminated as effectively and as efficiently as possible. The CDC strategy for implementation of the NEDSS system is to allow State and local health agencies to develop their own systems compatible with the established standards or utilize a CDC-developed version of NEDSS.

Currently, two States have fully implemented the CDC NEDSS system and 30 other States have requested assistance from CDC in installing this particular system. Other State and local health agencies continue to build or modify their disease surveillance systems to conform to our national standards.

Analysis and interpretation. CDC depends on its scientific and epidemiological expertise to interpret the volume of data received to ensure accurate conclusions are developed and disseminated to public health colleagues in a timely manner to impact health decisions. To ensure this effort is robust and can effectively deal with the increasing amount of data and information CDC receives, a biointelligence center is being conceptualized. This center would provide a centralized approach to analyzing and interpreting data and information, and will enable communications to ensure that this information and the conclusions drawn from the analysis are provided back to State and local health officials to enable appropriate action and support decisionmaking.

Information dissemination and knowledge management. Within this component of PHIN is CDC's health alerting capability, formally referred to as the Health Alert Network. Through this system CDC has the capacity to reach all State and local health officials and many other key responders such as hospitals, before, during and after any crisis that occurs within our communities. This system has been used to alert our colleagues of public health threats and emergencies over 150 times since September 11, 2001, reaching over 1.5 million recipients. Most recently the alerting capability was used to communicate critical health information in response to Hurricane Isabel.

CDC, through the PHIN, also supports the Epidemic Information Exchange Program, or EPI–x. EPI–x facilitates critical public health communication through a secure network between and among public health responders. Currently, there are approximately 1,800 users to subscribe to this service nationally.

Public health response. Since the majority of data management needs come after a disease is detected, CDC through the PHIN framework is developing new and improved systems to support public health response. Primarily, these efforts are supporting CDC's emergency operations, outfitting deployed staff with state-of-the-art information management tools, and supporting State and local efforts. These systems have been used to support the SARS outbreaks and special events such as the 2002 Winter Olympics in Salt Lake City. CDC has also developed the Pre–Event Vaccine System to support the National Smallpox Vaccination Program, which has proved and continues to prove to be a valuable information management tool.

The emergence of SARS, a previously unrecognized infectious disease, has provided a strong reminder of the threats posed by emerging infectious diseases and their global impact. CDC continues to build upon our strong relations with the World Health Organization, the Pan American Health Organization, and many other global partners to create a comprehensive global disease detection and reporting network. Currently, CDC has field epidemiology training programs, we call them FETPs, in 30 countries, supporting disease detection, providing an essential link in global surveillance.

CDC has also created two International Emerging Infections Programs, one in Thailand, which we created in 2001, and one in Kenya, which is projected to be up and running by the end of this calendar year. These programs will help to foster the next generation of international public health leaders, while providing high-quality disease surveillance data and rapid response capacity for new and emerging diseases.

This year we are also providing increased levels of funding to enhance disease detection and response capacity with our Mexican and Canadian neighbors to enhance the disease surveillance over the borders.

In conclusion, CDC is committed to working with Federal, State and local partners to protect the nation's health. Our best public health strategy against disease is to develop the systems needed to rapidly identify the causative organism, and then unleash a control and containment strategy that will minimize illness and death. Keep in mind that the astute clinician remains the critical link in this disease detection and reporting strategy. The first case of West Nile virus in 1999 and the first case of anthrax reported in early October 2001 were identified by these astute clinicians. Training and education of these frontline health protectors remains a high priority for the Department of Health and Human Services and CDC, and will continue to be a priority as we strive to improve all components of the nation's disease detection system. While we have made substantial progress towards enhancing the nation's capability to rapidly detect diseases within our communities, respond and contain outbreaks of disease, and recover from these tragic events, much remains to be done. CDC is extremely grateful for the congressional support received to date and looks forward to working with members of Congress, especially this committee, as we strive to protect the public's health from terrorism and other public health emergencies.

Thank you for your attention. I would be happy to take questions.

[The statement of Mr. Henderson follows:]

PREPARED STATEMENT OF JOSEPH M. HENDERSON, M.P.A

CDC's Disease Surveillance Systems Efforts

Good morning, Mr. Chairman and Members of the Subcommittee. I am Joseph M. Henderson, Director of the Office of Terrorism Preparedness and Emergency Response at the Centers for Disease Control and Prevention (CDC). As the nation's disease prevention and control agency, CDC, working with state and local public health agencies is charged with detecting and responding to illnesses, both man-

made and naturally occurring. This task is an integral part of CDC's overall mission to monitor and protect the health of the U.S. population.

Thank you for the opportunity to discuss how disease surveillance systems can prepare the nation for potential terrorist threats. "Disease surveillance systems" or disease detection systems, address one important aspect of our nation's overall public health preparedness. CDC, working with our federal, state, and local partners is working to build systems that can: (1) rapidly detect an event in our communities; (2) mobilize the appropriate response to contain the event, and (3) ensure affected communities return to a sense of normalcy. These are what we refer to as our foundations of public health readiness. My testimony will focus on rapid detection of an event, which is the topic of discussion for this sub-committee today.

National disease detection can best be described as the ongoing collection, analysis and dissemination of public health data related to illness and injury. These ongoing data collection and analysis activities enable public health officials to detect disease early, thus resulting in faster intervention to control and contain the consequences created by the causative agents. Without these early detection systems, the consequences of outbreaks of infectious disease and human exposures to agents such as chemicals and radiation would take a much greater toll by way of increased illness, injury, and in some cases death. Recent events, such as the SARS and Monkeypox outbreaks, have underscored the essential role early detection systems play in mobilizing rapid response. Detection of a disease almost always occurs at the local level where health care professionals encounter patients seeking medical assessment or treatment. A clinician's ability to quickly recognize and identify symptoms of unusual illnesses on the frontline has been critical to the CDC's ability to recognize unfolding disease events and implement containment measures to prevent further spread of disease, thus mitigating further harm to the public. Today, I will address three critical components of our disease detection systems: (1) Current state of national disease detection systems; (2) the Public Health Information Network—PHIN; and (3) global disease surveillance.

Current State of National Disease Detection Systems

One key to successful defense against any threat to the nation's public health, whether naturally occurring or deliberately caused, continues to be accurate, early recognition of the problem.

Awareness and diagnosis of a condition by a clinician or laboratory is a key element of our current disease detection systems. Clinicians and laboratories report diseases to state and local health departments, which in turn share information with CDC. CDC works with its public health partners to define conditions that should be reported nationally. Health departments share these definitions and guidelines with health care providers, infection control practitioners, emergency department physicians, laboratorians, and other members of the health care system to ensure accurate and timely reporting.

Many local reporters of disease incidence still report to public health authorities on paper via facsimile. If a case of illness is particularly unusual or severe (such as a case of anthrax), the local health care worker may call the local health department immediately to report the case. Current reporting systems are largely paper-based and burdensome to both providers and health departments, often resulting in reports which are neither complete nor timely. In addition to initial detection, these detection and reporting systems play a pivotal role in the detection of subsequent cases and help support the management of the event once a response/investigation are initiated. Such information is vital to coordinating response decisions, which ultimately lead to the containment of an outbreak.

A comprehensive surveillance system requires a strong foundation at all levels of local, state, and federal public health agencies. CDC has been working with state and local health agencies for many years to build the public health infrastructure to improve disease detection and reporting systems. Since September 11, 2001, the Administration has budgeted for and the Congress has appropriated over $2 billion to develop and sustain state and local public health readiness, specifically to enhance capacities to detect, respond, contain and recover from biological, chemical, and radiological acts of terrorism. States estimate that they are spending significant portions of this funding in both fiscal year 2002 and fiscal year 2003, to: 1) enhance epidemiological and surveillance capacity and 2) develop and leverage information technology and systems to support various public health functions.

Some examples of how states used their funding in these areas include:

- Michigan has begun implementation of a secure web-based disease surveillance system to improve the timeliness and accuracy of disease reporting.
- Missouri has implemented a new hospital tracking system to detect possible outbreaks by monitoring the number of patient admissions and ambulance di-

versions at hospitals. This system provides a way for hospitals to obtain instant messages and alerts.

• Virginia, Maryland, Washington DC, and Pennsylvania are all developing early warning systems based on symptom data from emergency departments to detect unusual patterns of illness and automatically alert hospitals and public health agencies when the incidence of disease exceeds a critical threshold. Use of such early warning systems might enable the earliest possible response and intervention before an outbreak or epidemic spreads.

Other related activities useful for early detection of emerging infections or other critical biological agents include CDC's Emerging Infections Programs (EIP). Through the EIP, state and local health departments receive funds to conduct population-based surveillance that goes beyond their routine function to develop "next generation" surveillance science, and often involves partnerships among public health agencies and academic medical centers. In addition, CDC has established networks of clinicians that serve as "early warning systems" for public health by providing information about unusual cases encountered in the clinical practices. As noted earlier, these relationships, particularly between health care providers and local health departments, are the foundation on which disease detection systems operate.

Public Health Information Network

For many years CDC has made significant achievements in building or enabling state and local health agencies to build information systems that support the practice of public health. However, many of these systems operate in isolation, not capitalizing on the potential for a cross-fertilization of data exchange. A crosscutting and unifying framework is needed to better integrate these data streams for early detection of public health issues and emergencies. The Public Health Information Network (PHIN) provides this framework. Through defined data, vocabulary standards and strong collaborative relationships, the PHIN will enable consistent collection and exchange of response, health, and disease tracking data among public health partners. Ensuring the security of this information is critical as is the ability of the network to work reliably in times of national crisis. PHIN encompasses four key components: (1) detection and monitoring;(2) analysis and interpretation; (3) information dissemination and knowledge management; and (4) public health response. Each of these components is briefly described below.

Public health information systems must support functions that include:

• Early event detection—BioSense is being developed to support early event detection activities associated with a possible Bioterrorism threat. Regional health data will be sent to authorized health officials detailing health trends that could be related to a possible Bioterrorism attack.

• Routine public health surveillance—NEDSS supports routine surveillance activities associated with the rapid reporting of disease trends to control outbreaks. The NEDSS platform allows states to enter, update and electronically transmit demographic and notifiable disease data.

• Secure communications among public health partners—Epi–X technology allows for the secure exchange of communications between participating public health partners via the web by providing up-to-the-minute information, reports, alerts, and discussions about terrorist events, toxic exposures, disease outbreaks, and other public health events.

• Management and dissemination of information and knowledge—HAN's architecture upgraded the capacity of state and local health agencies to communicate different health threats such as emerging infectious and chronic diseases, environmental hazards, as well as Bioterrorism related threats.

• Other functions include—Analysis and interpretation of relevant public health data and public health response systems.

PHIN will provide the framework for these functions to serve as part of an integrated and interoperable network critical in establishing a more effective public health system.

Detection and Monitoring

The CDC is in the proof-of-concept stage of BioSense—a proposal in development to enhance early event detection for public health emergencies such as bioterrorism. BioSense is proposed to enhance the nation's capabilities to rapidly detect and quantify public health emergencies by enabling rapid access to, and analysis of, diagnostic and pre-diagnostic health data. BioSense could establish the capability for rapid, around the-clock electronic transmission of data to local, state and federal public health agencies from national, regional and local health data sources such as clinical laboratories, hospital systems, health plans, DoD and VA medical treatment facilities, and pharmacy chains. Many of the pre-diagnostic data sources need to be

rigorously evaluated to determine which are most effective, but importantly, the initiative is based on the use of existing data and will not add to the reporting burden of clinical care or other healthcare professionals. BioSense data would not include patient names or personal identifiers, but may allow for the identification of early signs of a possible bioterrorist attack and facilitate appropriate public health investigation and follow-up by public health authorities. As proposed, BioSense will provide public health professionals a daily picture of normal diagnostic and therapeutic activities, provide indications of abnormal activities and also provide a way to rapidly investigate events to discern true concerns from false alarms.

Some early detection activities are currently occurring in local jurisdictions. BioWatch, which is a locally managed activity, is one source of data supporting BioSense. BioWatch involves the deployment of environmental air samplers in key locations throughout a city. Filters from these air samples are routinely gathered and analyzed by public health laboratories to determine if a potential release of a biological agent has occurred. Currently, many metropolitan areas within the United States participate in this project which is led by the Department of Homeland Security with support from CDC and our state and local public health partners.

CDC has initiated the development of the National Electronic Disease Surveillance System (NEDSS) which is a part of PHIN. The ultimate goal of NEDSS is the electronic, real-time reporting of information for public health action. NEDSS will include direct electronic linkages with the health care system allowing medical information, such as diagnostic tests, to be shared electronically with public health officials as soon as a clinical laboratory receives a specimen or makes a diagnosis of a condition of public health importance.

NEDSS integrates the numerous existing disease detection and monitoring systems using a standards-based approach with standards for data, information architecture, security, and information technology. This adherence to standards will ensure that data be entered once at the point of patient care, without a need for reentry of data at each level of reporting. Use of standards is critical in ensuring that public health practices use technology more effectively and collaboratively. The NEDSS strategy provides for state implementation of the CDC-developed version of NEDSS or state systems compatible with NEDSS. Some states are building their own NEDSS compatible systems. Two states have fully implemented the CDC NEDSS system and thirty other states have requested installation of the CDC-developed system.

As NEDSS progresses, we need to ensure that the data standards we use are compatible with those used in the health care delivery system. This will ensure ease of adaptation to future advancements in the field and ease of use for all levels of the clinical and public health systems. Moreover, NEDSS is fully consistent with Secretary Thompson's recently announced Consolidated Health Informatics (CHI) standards. These are health data interoperability standards established under one of the Administration's electronic government projects covering the federal health care enterprise. In addition, a standard information and security architecture will enable public health partners to share data while ensuring patients' privacy. The reliance on industry standards for information technology ensures the ability to interface with multiple commercial products to meet the needs of the public health community, including state-of-the-art analytic tools and geographic information system capacity.

Analysis and Interpretation

CDC depends on its scientific and epidemiological expertise to interpret the volume of data received to ensure accurate conclusions are developed and disseminated to our public health colleagues in a timely manner to impact public health decisions. As we develop more integrated systems and open new channels of data and information, more powerful tools and systems will be needed to rapidly and accurately perform this critical public health task. CDC's concept of this effort is a Bio–Intelligence center or BIC. The center would provide a centralized approach to analyzing and interpreting data and information and will assure appropriate communication channels are established to provide this information and analysis back to state and local health officials. In fiscal year 2004, CDC will continue to develop and investigate this concept.

Information Dissemination and Knowledge Management

Since September 11,2001, the anthrax attacks, and more recently the SARS and Monkeypox outbreaks, the general public, the first responder community, laboratory professionals, and our state and local partners have become more and more reliant upon the CDC website (*www.cdc.gov*) for critical public health information and

knowledge resources. CDC will continue to refine this national resource as we improve our ability to provide information across the web.

Within this particular component of the PHIN is CDC's health alerting capability(formerly referred to as the Health Alert Network). Through this program all fifty states, four large cities and eight territories are receiving funding and technical assistance from

CDC to strengthen core infrastructure for information access, communications, and training at the community level. This effort has built the foundation nationwide for: 1) continuous, high-speed Internet connectivity to support rapid information access; 2) broadcast capacity to support emergency communication; and 3) distance-learning infrastructure to support just-in-time training.

On September 11, 2001, CDC issued the first Health Alert Network message advising state and local health agencies of the need to enhance their disease detection systems to look for any unusual signs or symptoms related to a bioterrorist event. Since 9/11, CDC has issued over one-hundred fifty health alerts and advisories reaching 1.5 million health care professionals, as well as other first responder communities, on topics such as bioterrorism, West Nile virus, SARS, patient safety, and smallpox vaccination. Over 95% of our nation's public health agencies have the capability to receive and/or further distribute critical health alerts to their community stakeholders. The ability to access the web has allowed state and local health departments to utilize CDC's web based resources including CDC's secure communication system, Epi–X.

Epi–X (the Epidemic Information Exchange) is CDC's secure web-based communications system for public health professionals. This network provides secure communication of preliminary information regarding new health threats to a limited audience of authorized public health officials. Epi–X was created to provide a single source of up-to-the-minute alerts, reports, discussions, and comments contributed by their peers, and it is moderated by medical epidemiologists at CDC. Its primary goal is to inform health officials about important public health events, help them respond to public health emergencies, and to encourage exchange of information. Through Epi–X, health officials at CDC, other federal agencies, state and local health departments, poison control centers, and the military share preliminary health surveillance information—quickly and securely. Users are notified immediately of breaking health events as they occur. Currently, Epi–X has approximately 1800 users nationwide. Since its inception in December 2000, health officials have posted approximately 1500 reports of disease outbreaks. Epi–X highlights include local and national responses to terrorism, responses to emerging diseases such as severe acute respiratory syndrome (SARS) and monkeypox, West Nile virus surveillance, influenza surveillance, foodborne outbreaks and food recalls that affected residents in multiple states, and investigations of travelers with contagious illnesses.

Public Health Response

Since the majority of the data management needs come after disease is detected, CDC through PHIN is investing in information systems to support our public health response teams, our Director's Emergency Operations Center in Atlanta and to assist state and local health agencies in tracking and managing vital public health information before, during, and after an event has occurred. These systems have been used to support the SARS outbreak, special events such as the 2002 Winter Olympics in Salt Lake City, and other events that could potentially be targets of a terrorist attack.

Global Disease Surveillance

The emergence of SARS, a previously unrecognized infectious disease outbreak, has provided a strong reminder of threats posed by emerging infectious diseases. In March 2003, the Institute of Medicine (I0M) published *Microbial Threats to Health: Emergence, Detection, and Response,* a report describing the spectrum of microbial threats to national and global health, factors affecting their emergence or resurgence, and measures needed to address them effectively. Although much progress has been made, especially in the areas of strengthened surveillance and laboratory capacity, CDC is taking steps to make further improvements both domestically and internationally.

CDC is intensifying its efforts to work with the World Health Organization (WHO) and other partners to create a comprehensive global network that detects and controls outbreaks before they grow into worldwide pandemics. Currently, there are Field Epidemiology Training Programs (FETP's) in thirty countries throughout the world that support disease detection activities and provide an essential link in global surveillance. The FETP program is modeled after CDC's Epidemic Intelligence Service (EIS) training program which focuses on training public health practitioners in epidemiology and surveillance and their application as a means to detect and control outbreaks and to implement interventions to prevent the further spread of disease. Additionally, there is a concerted effort to develop and expand regional disease surveillance networks that include less developed nations as members.

CDC has also created two International Emerging Infections Programs (IEIPs)—one in Thailand (established in 2001) and one in Kenya (scheduled to open in 2003)—that are modeled on the domestic EIP Programs described earlier which have been so successful in the United States. The IEIPs will help to foster the next generation of international public health leaders while providing high quality disease surveillance data and rapid response capacity for new and emerging diseases.

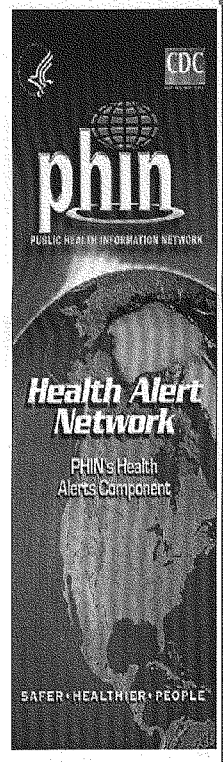
Conclusion

CDC is committed to working with federal, state and local partners to protect the nation's health. Our best public health strategy against disease is the development, organization, and enhancement of public health disease detection systems, tools, and the people needed to wield them. The astute clinician remains the critical link in disease detection and reporting. The first case of West Nile in 1999, and the first case of anthrax reported in early October 2001, were identified by astute clinicians. Training and education of these front-line health protectors remains a high priority for CDC and will continue to be a priority as we strive to improve all components of the nation's disease detection systems.

While we have made substantial progress towards enhancing the nation's capability to rapidly detect disease within our communities, improving our response and containment strategies, and developing plans to recover from tragic events, much remains to be done. CDC is very grateful for the congressional support received to date and looks forward to working with the Members of Congress, especially this committee as we strive to protect the public's health from terrorism and other public health emergencies.

Thank you very much for your attention. I will be happy to answer any questions you may have.

Health Alert Network (HAN)



Background

CDC's Health Alert Network (HAN) is dedicated to strengthening the core public health infrastructure for information access, communications, and distance learning at the state and community levels. Through continuous, high-speed internet connectivity and broadcast capacity to support emergency communication, HAN provides the national public health system with a network of public health officials and other first-responders continuously connected to the information vital to emergency and non-emergency public health practice.

Purpose

The purpose of the Health Alert Network (HAN) is to build a nationwide network of strong public health agencies which can effectively serve as the nation's frontline defense against terrorism and other public health threats. The program intends to ensure that each community has rapid and timely access to emergent health information; a cadre of highly-trained professional personnel; and evidence-based practices and procedures for effective public health preparedness, response, and service on a 24/7 basis.

History of Development

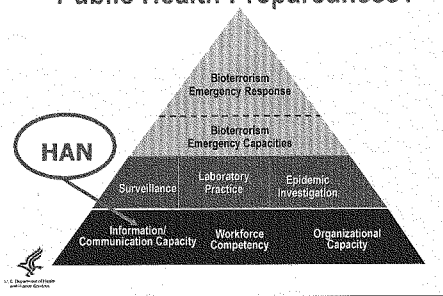
HAN was initiated in 1999, when an initial group of 36 grantees (33 States and 3 City/County Health Departments) were funded to develop capacity at the State and Local levels for continuous, high-speed access to vital public health information, and the capacity to broadcast information in support of emergency communications. In addition, the initial HAN program included support of distance-learning capacities (which has since moved to Focus Area G of the BT Cooperative Agreement). Since the initial cooperative agreement, HAN has grown to include all 50 States and 8 US Territories/Jurisdictions, as well as New York City, Los Angeles County, Chicago, and Washington, DC. Well over $300 Million has been spent on information and communication infrastructure development programs at the State and Local levels.

Health Alert Network (HAN)

Current Status

Currently, HAN is a strong national program, providing vital health information and the infrastructure to support the dissemination of that information at the State and Local levels, and beyond. A vast majority of the State-based HAN programs have over 90% of their population covered under the umbrella of HAN. The HAN Messaging System currently directly and indirectly transmits Health Alerts, Advisories, and Updates to over one million recipients. The current system is being phased into the overall PHIN messaging component.

How does HAN support Public Health Preparedness?



Future Plans

HAN will continue to be an active asset in the overall PHIN Initiative. Key components of HAN will include:

- **Focus Area E Technical Assistance**
  - *Continuous Internet access*
  - *Interoperable, redundant emergency communications*
  - *Advanced Practice sites*
  - *Network Testing*
  - *Local Broadcast capacity*
- **Message Dissemination**
- **Terrorism Preparedness**
- **NEDSS Ambassadors**
- **Collaborate with IRMO:**
  - *National directory pilots at the state level*
  - *National messaging protocol*
  - *Messaging/systems evaluation*
  - *State exchange and data privacy agreements*

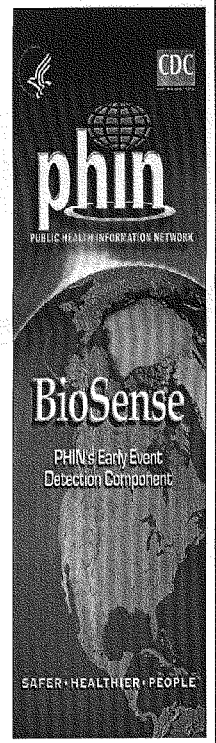
Key Contact Information

Website: www.phppo.cdc.gov/HAN
Names: David Clark, Team Lead
Jay Allen, Rosalyn Bell, Juanita Crowder, Susan Shaw, Michael Smiley
Phone: 770-488-2425
e-mail: healthalert@cdc.gov

How it fits into the PHIN Concept

HAN will function as PHIN's Health Alert component. This includes collaborating with federal, state, and city/county partners to develop protocols and stake holder relationships that will ensure a robust interoperable platform for the rapid exchange of public health information.

BioSense



Brief Description

Elevated concerns over Bioterrorism and rapidly developing outbreaks in the U.S. warrants looking for new approaches for early event detection.

BioSense is one of several national initiatives to improve the nation's preparedness for identifying and handling a Bioterrorism event.

BioSense will improve early detection though the implementation of near real time reporting of health data, the implementation of enhanced connections between clinical care and public health, and the advancement of early detection analytics..

Purpose

BioSense will provide:

- Early event detection critical for Bioterrorism and "routine" public health event management
- Aggregation of diagnostic and pre-diagnostic data available from existing electronic sources
- Real-time data acquisition and analysis technology
- Coordination of early event detection to establish a national safety net and facilitate use of national and regional data sources

History of Development

Phase one of BioSense will provide a view of data from national sources, using web-based information and analytical capability, for public health officials relating to possible bioterrorism events in their jurisdiction.

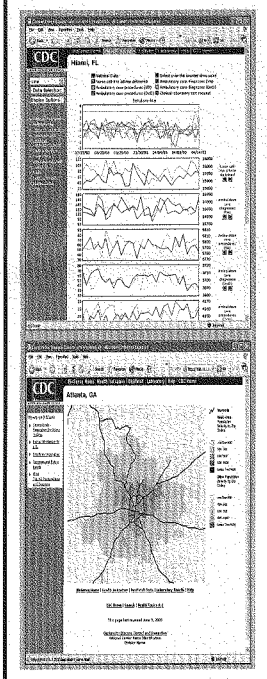
Phase II will continue to evolve and advance visualization and analysis capabilities at all levels of public health, provide granular data to local detection systems, and increase the amount of clinical data that can be provided to detection systems from national, regional and local clinical care (using identified data exchange standards).

BioSense **Page 2**

Current Status

BioSense Phase One will be available for use in October of 2003. Phase One will provide real-time access to time series and geographic views of indicators for all involved jurisdictions.

Phase One data sources will include; DoD medical treatment facilities in U.S., VA medical facilities, 18 Laboratory Response Network Labs for BioWatch and Category A agent result reporting, data from over 10,000 OTC retailers nationwide, and national clinical lab tests orders. Other clinical and Health Plan data are to be added soon.



Future Plans

A next step for BioSense will be to connect relevant regional data from hospital systems, health plans, and clinical information systems vendors.

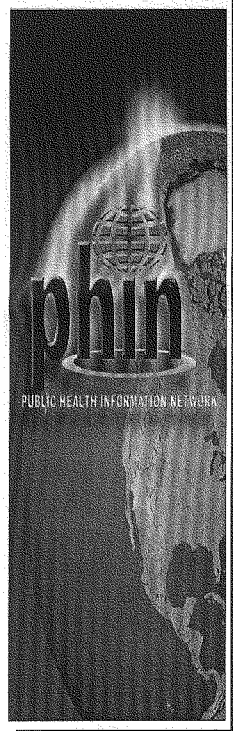
BioSense will work to facilitate electronic public health investigation of suspicious health events and advance analytic and alerting capabilities.

BioSense will also work to standardize interchange of data with existing early detection systems.

Key Contact Information:
John W. Loonsk, MD
Associate Director for Informatics,
Centers for Disease Control and Prevention
Phone: 404-639-7600
e-mail: jloonsk@cdc.gov

How it fits into the PHIN Concept:
Early event detection is a key component of PHIN. BioSense is being developed to support early event detection activities associated with a possible bioterrorism threat, but needs to seamlessly integrate with response and other related systems. PHIN will provide the framework for critical public health functions such as BioSense to serve as part of an integrated and interoperable network critical in developing a more effective and response-oriented public health system.

PHIN Vocabulary and Thesaurus



Background

Using, developing, and distributing standardized terminology for public health purposes is a key component of PHIN.

Agreed-upon and readily-comprehensible vocabulary is critical to support information flows within public health and between public health and its partners. Hence many stakeholders look to CDC and the PHIN initiative for leadership, technical assistance, and participation in vocabulary development.

Purpose

If information in multiple locations is to be searched, synthesized, or shared efficiently and effectively, then vocabulary standards must be fostered and implemented.

PHIN vocabulary initiatives and projects are designed to meet cross-cutting needs as well as specific programmatic requirements at the local, state, and national levels.

These initiatives and projects are designed to serve the goal of providing timely public health information to all who need it.

Development Principles

The Public Health Information Network (PHIN), through defined data and vocabulary standards and strong collaborative relationships, will enable consistent exchange of response, health, and disease tracking data between public health partners using existing systems such as PHIN MS, NEDSS, HAN, EPI-X, and vocabulary services. PHIN is composed of five key components: detection and monitoring, data analysis, knowledge management, alerting, and response. PHIN seeks to promote and use currently available terms and codes to the fullest extent possible and extend vocabulary standards when gaps need to be filled to meet public health requirements. PHIN also is developing processes and a technical infrastructure for rapid distribution of vocabulary and vocabulary updates to users at all geographic levels: local, state, and national. The particulars of terminology development for PHIN involves participation by a wide range of programs and people, with input from subject matter experts, vocabulary specialists and information system developers.

September 5, 2003

PHIN Vocabulary and Thesaurus

Current Status

Initiatives and projects currently under way include:

- *Vocabularies for the National Electronic Disease Surveillance System (NEDSS) and Laboratory Response Network (LRN):* Terms and codes to support disease surveillance and response systems, including electronic results reporting from laboratories to public health and notifiable disease reporting from state systems to CDC.
- *PHIN Notifiable Condition Mapping Tables:* Laboratory test and results codes mapped to notifiable disease conditions, presented in a set of tables, designed to facilitate a nationally standardized approach to electronic laboratory reporting.
- *A thesaurus of terms used by CDC programs on their web pages:* This is a major feature of the current CDC web site redesign. The thesaurus will link terms used by different programs, provide synonyms and conceptual relationships between terms, and facilitate term-based searches.

Future Plans

In addition to further development and enhancements of projects under way, plans call for a Vocabulary Distribution System. This is a web-based system under development for rapid distribution of vocabulary and vocabulary updates (including terms and codes for use in the NEDSS and LRN applications). Plans also call for web browsing and web services capabilities for vocabulary distribution to all interested public health partners.

As new versions of vocabularies are developed to meet PHIN requirements, these updates will be available or disseminated through the Vocabulary Distribution System. Efforts are under way to implement a public health sector-wide approach to vocabulary development and management. Activities include selecting a vocabulary management tool for use across CDC programs and establishing a single vocabulary repository for use in conjunction with the Vocabulary Distribution System.

Key Contact Information:

Website: **http://www.cdc.gov/phin/data models/index.htm**

Names: Daniel A. Pollock, M.D., Mamie J. Bell, MLn (Web redesign thesaurus)

Phone: (404) 639-7715 (DAP)
(404) 639-7263 (MJB)

e-mail: dpollock@cdc.gov
zvt9@cdc.gov (MJB)

How it fits into the PHIN Concept

Vocabulary services and development are an integral part of PHIN. They are a key component of a standards-based approach to public health information systems development and deployment and relate specifically to the following PHIN functions:

1 - *The Automated Exchange of Data Between Public Health Partners*
2 - *The Use of Electronic Clinical Data for Event Detection*
3 - *Manual Data Entry for Event Detection and Management*
4 - *Specimen and Lab Result Information Management and Exchange*
8 - *Public Health Information Dissemination and Alerting*

For More Information:
http://www.cdc.gov/phin/architecture/index.htm

Public Health Information Network

Early Event Detection
BioSense

Surveillance
NEDSS

Secure
Communications
Epi-X

Analysis &
Interpretation
BioIntelligence
Center Technology

Information
Dissemination & KM
CDC Website
HAN

PH Response
Lab, Outbreak
Management, Vaccine
administration, etc.

phin

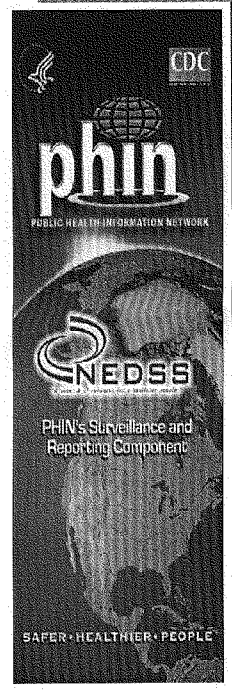
PUBLIC HEALTH INFORMATION NETWORK

Federal Health
Architecture &
Consolidated
Health Informatics

SAFER • HEALTHIER • PEOPLE

CDC

National Electronic Disease Surveillance System (NEDSS) Base System (NBS)



Background

NEDSS is a both a concept for integrated health and surveillance information systems and the NEDSS Base System is a practical application of the concept.

NEDSS is based on the following principles:

- Use industry standards;
- Rely on off-the-shelf software, e.g. web browsers, reporting tools (SAS)
- Transmit information securely across the Internet;
- Design for usability and common look and feel;
- Create standard reporting
- Make CDC reporting a by-product of disease surveillance
- Designed for Open Platform

Purpose

NEDSS Base System provides functional applications to allow users to perform information collection, storage and retrieval, and reporting to support health surveillance and investigation functions.

NBS includes point in time demographics, remote and manual morbidity and lab report entry, electronic lab reporting and system security based on user-defined jurisdictions, programs, roles and activities. NBS improves the timeliness of reporting public health events, maintains data integrity and provides consistent and structured data for analysis ease of operation. NBS is also supports the use of vocabulary standards through system reference table and look-up capability.

History of Development

- First Joint Application Design (JAD) sessions in December 2000
- Prototype reviewed by users July 2001
- Test release ready in July 2002
- NBS Release 1.0 ready in October 2002
- NBS installed and running in first state (NE) January 2003
- NBS In use in first state (NE) May 2003 and second state (SC) in August 2003
- NBS Release 1.1 ready in September 2003

Elements of the NEDSS Architecture

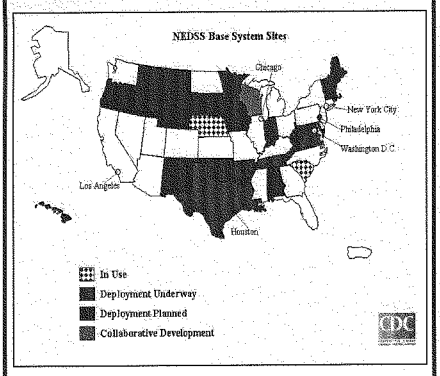
- Standards-based Electronic Lab Reporting (ELR) and messaging
- Web browser-based data entry and data management
- Central, integrated operational data store
- Data transformation and exchange functionality
- Analysis and reporting capability
- Shareable public health directory
- HIPAA-compliant security infrastructure and policies, including two-factor authentication
- Contemporary programming practices for modular, cross-platform development

September 5, 2003

NEDSS Base System (NBS) Page 2

Current Status

NBS Release 1.02 is currently being used in Nebraska and South Carolina. It is in various stages of deployment in Tennessee, Louisiana, Virginia, Indiana and Texas. Release 1.1 will be ready in September 2003 and will include new functionality, usability enhancements, architectural improvements and better security for preventing virus and worm attacks. The map below shows the status of all NBS sites.



Future Plans

Release 1.1.1 will be delivered in the late fall. This release adds significant reporting capabilities including the ability to capture and report locally defined fields (offering state and local users the opportunity to use the generic forms to capture and report information for emergency disease surveillance).

Finally, current plans call for deployment of the Release 1.1.1 NEDSS Base System in 15 states and one city within the next year.

Also being developed is Release 1.2 which will provide services to PAM Applications: STD, Lead, TB, Foodborne, and others over time. Current requirements under review for Release 1.2 include adding functionality for System Reference Table versioning, filtering, administration and distribution.

Key Contact Information:

Website: http://www.cdc.gov/PHIN

Names: Jason Hall, Katherine Robinson

Phone: 404-371-5366, 404-202-6247

e-mail: zfr9@cdc.gov, kad2@cdc.gov

How NEDSS and the NBS fit into the PHIN Concept

NEDSS is a disease surveillance and investigation component of PHIN. Several of the PHIN functions and specifications were either taken from or influenced by the NEDSS Systems Architecture. The NBS is a specific incarnation of NEDSS, i.e. a system developed according to the NEDSS Systems Architecture and PHIN functions and specifications.
http://www.cdc.gov/phin/architecture/index.htm for more information.

Epi-X™

The Epidemic Information Exchange (Epi-X)

What is *Epi-X*? *Epi-X* is CDC's web-based communications system for public health professionals. The network provides secure communication of preliminary information regarding new health threats to a limited audience of authorized public health officials. Information flows from the network to users and vice versa.

Through *Epi-X*, health officials at CDC, state and local health departments, poison control centers, and the military share preliminary health surveillance information — quickly and securely. Users are notified immediately of breaking health events as they occur. Key features of *Epi-X* include 24/7 scientific and editorial support, controlled user access, digital credentials and authentication, rapid outbreak reporting, peer-to-peer consultation, and CDC-assisted coordination of investigations.

Who's participating in *Epi-X*? To ensure the exchange of preliminary information remains secure, participation in *Epi-X* is limited to public health officials designated by each health agency. These officials are engaged in identifying, investigating, and responding to health threats. The technology that supports *Epi-X* makes the system available to these individuals while in the field, in the laboratory, at the office, or at home. Currently, *Epi-X* has approximately 1800 users nationwide.

What's being shared on *Epi-X*? *Epi-X* supports postings and discussions about disease outbreaks and other health events that potentially involve multiple jurisdictions. Since its inception in December 2000, health officials have posted approximately 1500 reports of disease outbreaks. *Epi-X* highlights include local and national responses to terrorism, responses to emerging diseases such as severe acute respiratory syndrome (SARS) and monkeypox, West Nile virus surveillance, influenza surveillance leading to the discovery of a new strain, foodborne outbreaks and food recalls that affected residents in multiple states, and investigations of travelers with contagious illnesses.

When is information exchanged on *Epi-X*? *Epi-X* provides rapid communications whenever there is a public health need. *Epi-X* scientific staff are available 24 hours a day, 7 days a week to provide assistance in editing and posting reports on the secure web site and to notify users routinely (by e-mail) or emergently (by pager, telephone, and e-mail) about acute health events.

How and Why is *Epi-X* "secure" --- what does that mean? To protect the sensitive nature of the preliminary information it provides, *Epi-X* uses the highest level of content security technology available. Contributors of information also specify whether *Epi-X* users can share the information with others outside the system. Users also sign a security agreement that describes their responsibilities in keeping the information of *Epi-X* secure.

In addition, all *Epi-X* users are designated public health officials who understand and respect the secure nature of the communications that take place on the system. Ultimately, the activities on *Epi-X* foster a coordinated response to public health events. The results? Effective interventions and accurate communications.

Why is information exchanged on *Epi-X*? *Epi-X* was created to provide public health officials with a single source of up-to-the-minute alerts, reports, discussions, and comments contributed by their peers, and moderated by medical epidemiologists and laboratorians at CDC. Its primary goal is to inform health officials about important public health events, to help them respond to public health emergencies, and to encourage professional growth and exchange of information. *Epi-X* also helps to ensure accurate communications to the public (when appropriate), through *MMWR* and other sources.

For additional information, contact *Epi-X*, at **epixhelp@cdc.gov** or **404-639-3762**, Monday through Friday from 8:00 a.m. to 4:30 p.m. EST.

CDC
Centers for Disease Control and Prevention

August 8, 2003

Epi·X™ The Epidemic Information Exchange

Epi-X in Brief

Epi-X is CDC's secure Web-based communications network for public health officials. Through the use of advanced Internet and communications technologies, *Epi-X* users anticipate and respond to emerging health events.

Epi-X is the only system that links the command centers at HHS and CDC with state bioterrorism surveillance and response programs.

Epi-X users create reports, comment on reports, and immediately notify users of breaking public health news.

Epi-X users receive assistance with report preparation from *Epi-X* scientific staff 24 hours a day, seven days a week.

Epi-X sends a daily e-mail to notify users of routine public health events. Users customize *Epi-X* so they receive e-mail only when a report is in their area of interest. In the event of a public health emergency, *Epi-X* notifies all users immediately via cell phone, telephone and pager.

Epi-X launched in December 2000. Since that date, 49 states and WHO have posted reports on *Epi-X*. These reports safely and securely communicated information about outbreaks and bioterrorism events.

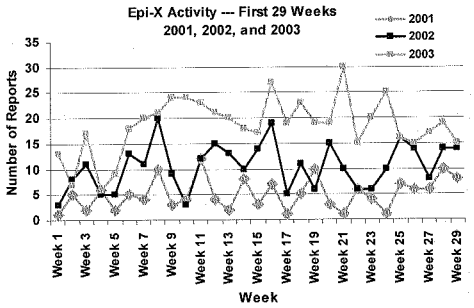
Epi-X Users

Epi-X users are top public health professionals in the United States. As of August 26, 2003, *Epi-X* users are from the following organizations and backgrounds:

CDC	787
Epidemic Intelligence Service Officers	155
Non-CDC	906
Bioterrorism Coordinators	73
State Epidemiologists	61
State Public Health Veterinarians	35
State Laboratory Directors	31
State Health Officers	31
Deputy State Health Officers	15
Poison Control Center Directors	39
Military Personnel	11

Epi-X Reports

Epi-X continues to grow. Steady growth can be seen by comparing activity for the first 29 weeks of each calendar year from 2001 through 2003.



During the first 29 weeks of 2001, 146 reports were posted.
During the first 29 weeks of 2002, 306 reports were posted.
During the first 29 weeks of 2003, 537 reports were posted.

Epi-X at a Glance

As of August 26, 2003:

- Reports since launch – 2459
- *Epi-X* users – 1793
- *Forum* only users – 592
- Most frequently used *Epi-X* report category – Infectious Disease
- Most frequently used *Forum* conference – West Nile Virus
- Average time from submission of a standard report to posting (April - June 2003) – 4 hours, 12 minutes

U. S. Department of Health and Human Services

CDC
Centers for Disease Control and Prevention

>>> https://epix.cdc.gov

Mr. SHADEGG. Thank you, Mr. Henderson.

Next we will hear from Janet Heinrich, director of public health issues at the U.S. General Accounting Office.

STATEMENT OF MS. JANET HEINRICH, DIRECTOR, PUBLIC HEALTH ISSUES, U.S. GENERAL ACCOUNTING OFFICE

Ms. HEINRICH. Mr. Chairman and members of the subcommittee, I appreciate the opportunity to discuss State and local preparedness to manage outbreaks of infectious diseases, be they naturally occurring or the product of bioterrorism.

Recent challenges such as the SARS outbreak and the anthrax incidents of 2001 have raised concerns about the nation's preparedness to manage a disease outbreak or a bioterrorism event. Existing surveillance systems have weaknesses such as chronic underreporting and outdated laboratory facilities, which have raised concerns about the ability of State and local agencies to quickly detect infection disease outbreaks.

My remarks will focus on the preparedness of State and local public health agencies for responding to infectious disease outbreaks, and the contributions of hospital preparedness for such an event. To assess bioterrorism preparedness, we conducted visits to seven cities and their respective State governments from December 2001 through March 2002. We are currently reviewing the summer 2003 CDC and HRSA applications and progress reports, as well as interviewing State and local officials from these jurisdictions, and from a few additional States and two major municipalities.

In order to be prepared for infectious disease outbreaks, State and local public health agencies need to have several basic capabilities such as disease surveillance systems and epidemiologists to detect clusters of suspicious symptoms or diseases, laboratories with adequate capacity and staff to test clinical and environmental samples, and communications systems to easily communicate with other health care providers. Hospitals need the necessary capacity to treat infectious diseases, and emergency department staff needs to be able to recognize and report unusual illness patterns.

State and local officials for the cities we visited recognized and were attempting to address inadequacies in their surveillance systems. They were developing systems using electronic databases and several cities were evaluating the use of non-traditional data sources such as pharmacy sales. Officials reported that CDC funds have enabled them to make improvements, including the Web-based reporting that we just heard about and active surveillance.

According to preliminary data from our review this year, improvements have also been made in the laboratory infrastructure, including upgrading facilities, purchasing reagents and equipment, and improving capabilities to test for select biologic agents. Most of the cities we visited have purchased communication systems that allow officers and officials from different organizations to communicate with one another in an emergency. In addition, they have been working with CDC to build their capability with HAN, the Health Alert Network, which provides the high-speed Internet connectivity.

However, workforce shortages continue to be a major concern. Officials report concerns about not having enough epidemiologists to

complete investigations, as well as retaining trained laboratory personnel. A continuing concern for response organization officials was the lack of planning at the regional level. There continues to be a lack of coordination between States that would severely hamper a response to an infectious disease outbreak.

Our surveillance capabilities also depend in large part on the capabilities of hospitals and trained staff in emergency departments. In our survey of over 2,000 metropolitan hospitals most hospitals reported training staff in biological agents, but fewer than half have participated in drills or exercises related to bioterrorism. We also found that most emergency departments have experienced some degree of overcrowding, which is more pronounced in the largest metropolitan areas and where there has been high population growth. Hospital capacity is expected to be strained if, for example, there were another SARS outbreak during the winter months when you have peak loads of patients with influenza.

In conclusion, efforts at the State and local level have improved their ability to identify and respond to infectious disease outbreaks and bioterrorism. Despite these improvements, gaps in preparedness remain. Some disease surveillance systems need to be upgraded. There are shortages of key personnel and hospital emergency departments across the country lack capacity for managing infectious disease outbreaks.

Mr. Chairman, that completes my prepared statement. I am happy to answer any questions you may have.

[The statement of Ms. Heinrich follows:]

UNITED STATE GENERAL ACCOUNTING OFFICE

INFECTIOUS DISEASES

Gaps Remain in Surveillance Capabilities of State and Local Agencies

PREPARED STATEMENT OF JANET HEINRICH, DIRECTOR, HEALTH CARE—PUBLIC HEALTH ISSUES

Mr. Chairman and Members of the Subcommittee:

I appreciate the opportunity to be here today to discuss the work we have done on state and local preparedness to manage outbreaks of infectious diseases, which may be naturally occurring or the product ofbioterrorism. In order to be adequately prepared for such a major public health threat, state and local public health agencies need to have several basic capabilities, including disease surveillance systems.[1] I Surveillance is public health officials' most important tool for detecting and monitoring both existing and emerging infections. Effective surveillance can facilitate timely action to control outbreaks and inform allocation of resources to meet changing disease conditions. Without adequate surveillance, local, state, and federal officials cannot know the true scope of existing health problems and may not recognize new diseases until many people have been affected.

Recent challenges, such as the SARS[2] outbreak and the anthrax incidents in the fall of 2001, have raised concerns about the nation's preparedness to manage a disease outbreak or a bioterrorist event should it reach large-scale proportions. Existing surveillance systems have weaknesses, such as chronic underreporting and outdated laboratory facilities, which raise concerns about the ability of state and local agencies to detect emerging diseases or a bioterrorist event. As a result, state and local response agencies and organizations have recognized the need to strengthen

[1] Disease surveillance uses systems that provide for the ongoing collection, analysis, and dissemination of health-related data to identify, prevent, and control disease.

[2] SARS is the abbreviation for severe acute respiratory syndrome.

their public health infrastructure and capacity. The improvements they are making are intended to strengthen their ability to identify and respond to major public health threats, including naturally occurring infectious disease outbreaks and acts of bioterrorism.

To assist the Subcommittee in its consideration of our nation's capacity to detect and monitor an outbreak of an infectious disease, my remarks today will focus on (1) the preparedness of state and local public health agencies for responding to an infectious disease outbreak, and (2) the contributions of hospitals to preparedness for an infectious disease outbreak.

My testimony today is based largely on our recent work, including a report on state and local preparedness for a bioterrorist attack.[3] For that report, we conducted site visits in December 2001 through March 2002 to seven cities and their respective state governments. We also reviewed each state's spring 2002 applications for bioterrorism preparedness funding to the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and Health Resources and Services Administration (HRSA), and each state's fall 2002 progress report on the use of that funding. In addition, I will discuss some preliminary findings trom our current work that provides updated information on the preparedness of state and local public health agencies. For that work, we are reviewing the summer 2003 applications and progress reports and interviewing public health officials trom 10 states and two major municipalities. I also will present some findings from a survey we conducted in 2002 on hospital emergency department capacity and emergency preparedness.[4] We conducted our work in accordance with generally accepted government auditing standards.

In summary, state and local officials in the cities we visited reported varying levels of public health preparedness to respond to outbreaks of emerging infectious diseases such as SARS. They recognized gaps in preparedness elements that have been difficult to address, including the disease surveillance and laboratory systems and the response capacity of the workforce. They also were beginning to address gaps in preparedness elements such as communication. We found that planning for regional coordination was lacking between states.

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[3] U.S. General Accounting Office, *Bioterrorism: Preparedness Varied across State and Local Jurisdictions,* GAO–03–373 (Washington, D.C.: Apr. 7, 2003).

[4] Findings from the survey include those related to emergency department capacity, which we reported in U.S. General Accounting Office, *Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities,* GAO–03–460 (Washington, D.C.: Mar. 14, 2003) and to hospital emergency preparedness for mass casualty incidents, which we reported in U.S. General Accounting Office, *Hospital Preparedness: Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities/or Bioterrorism Response,* GAO–03–924 (Washington, D.C.: Aug.6,2003).

Because those with symptoms of an infectious disease might go to emergency departments for treatment, hospital personnel would likely be some ofthe first healthcare workers with the opportunity to identify an infectious disease outbreak. Therefore, the disease surveillance capacities of many state and local public health systems may depend, in part, on the surveillance capabilities of hospitals. Most hospitals reported training their staff and planning coordination efforts with other public health entities. However, even with these preparations in place, hospitals lacked the capacity to respond to large-scale infectious disease outbreaks.

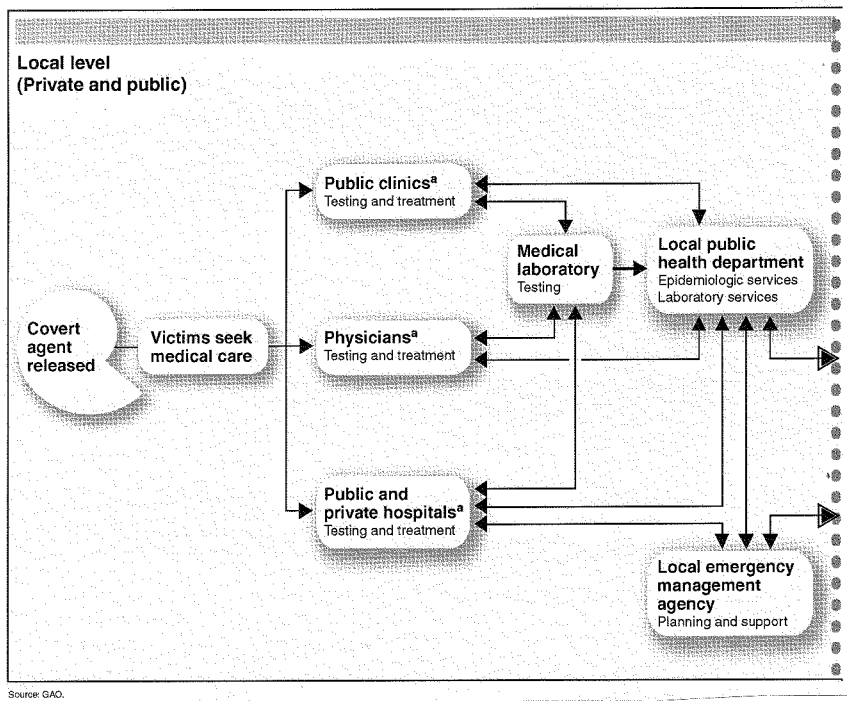
BACKGROUND

Infectious diseases include naturally occurring outbreaks, such as SARS, as well as diseases from biological agents that are intentionally released by a terrorist, such as smallpox.[5] An infectious disease outbreak, either naturally occurring or from an intentional release, may not be recognized for a week or more because symptoms may not appear for several days after the initial exposure, during which time a communicable disease could be spread to those who were not initially exposed.

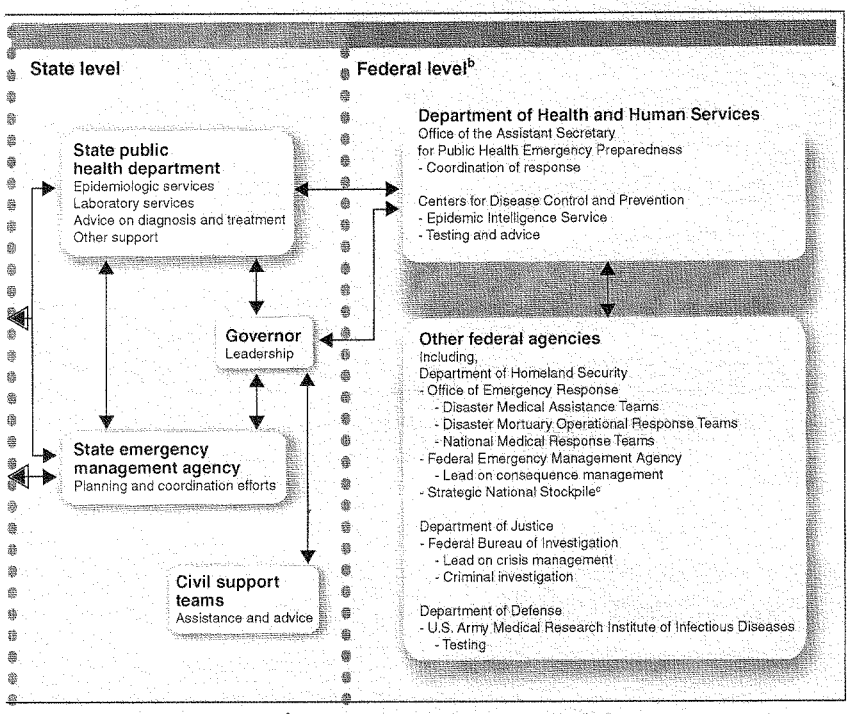
The initial response to an infectious disease of any type, including a bioterrorist attack, is generally a local responsibility that could involve multiple jurisdictions in a region, with states providing additional support when needed. Figure 1 presents the probable series of responses to a covert release of a biological agent. Just as in a naturally occurring outbreak, exposed individuals would seek out local health care providers, such as private physicians or medical staff in hospital emergency departments or public clinics. Health care providers would report any illness patterns or diagnostic clues that might indicate an unusual infectious disease outbreak associated with the intentional release of a biologic agent to their state or local health departments.

[5] CDC developed a critical agent list that focuses on the biological agents that would have the greatest impact on public health. This list includes a category of agents identified by CDC as most likely to be used in a bioterrorist attack and includes communicable diseases such as smallpox and pneumonic plague.

Figure 1: Local, State, and Federal Entities Involved in Response to the Covert Release of a Biological Agent



Source: GAO.



[a]Health care providers can also contact state entities directly.

[b]Federal departments and agencies can also respond directly to local and state entities.

[c]The Strategic National Stockpile, formerly the National Pharmaceutical Stockpile, is a repository of pharmaceuticals, antidotes, and medical supplies that can be delivered to the site of a biological (or other) attack.

In order to be adequately prepared for emerging infectious diseases in the United States, state and local public health agencies need to have several basic capabilities, whether they possess them directly or have access to them through regional agreements. Public health departments need to have disease surveillance systems and epidemiologists to detect clusters of suspicious symptoms or diseases in order to facilitate early detection of disease and treatment of victims. Laboratories need to have adequate capacity and necessary staff to test clinical and environmental samples in order to identify an agent promptly so that proper treatment can be started and infectious diseases prevented from spreading. All organizations involved in the response must be able to communicate easily with one another as events unfold and critical information is acquired, especially in a large-scale infectious disease outbreak.

In the event of an outbreak, hospitals and their emergency departments would be on the front line, and their personnel would take on the role of first responders. Because hospital emergency departments are open 24 hours a day, 7 days a week, exposed individuals would be likely to seek treatment from the medical staff on duty. Staff would need to be able to recognize and report any illness patterns or diagnostic clues that might indicate an unusual infectious disease outbreak to their state or local health department. Hospitals would need to have the capacity and staff necessary to treat severely ill patients and limit the spread of infectious disease.

The federal government also has a role in preparedness for and response to major public health threats. It becomes involved in investigating the cause of the disease, as it is doing with SARS. In addition, the federal government provides funding and resources to state and local entities to support preparedness and response efforts. CDC's Public Health Preparedness and Response for Bioterrorism program provided funding through cooperative agreements in fiscal year 2002 totaling $918 million to states and municipalities to improve bioterrorism preparedness and response, as well as other public health emergency preparedness activities. The funding supported development and improvements in a number of areas CDC considers critical to preparedness and response, including surveillance capacity to rapidly detect outbreaks of illness that may be the result of bioterrorism or other public health threats.

HRSA's Bioterrorism Hospital Preparedness Program provided funding through cooperative agreements in fiscal year 2002 of approximately $125 million to states and municipalities to enhance the capacity of hospitals and associated health care entities to respond to bioterrorist attacks. Earlier this month, HHS announced that approximately $870 million and $498 million have been provided for fiscal year 2003 through the CDC and HRSA programs, respectively, to states and municipalities to continue these efforts.

DESPITE IMPROVEMENTS, GAPS REMAIN IN DISEASE SURVEILLANCE CAPABILITIES OF STATE AND LOCAL PUBLIC HEALTH AGENCIES

In the cities we visited, state and local officials reported varying levels of public health preparedness to respond to outbreaks of emerging infectious diseases such as SARS. They recognized gaps in preparedness elements that have been difficult to address, including the disease surveillance and laboratory systems and the response capacity of the workforce. They also were beginning to address gaps in preparedness elements such as communication. We found that planning for regional coordination was lacking between states.

PROGRESS HAS BEEN MADE IN ELEMENTS OF PUBLIC HEALTH PREPAREDNESS, BUT GAPS REMAIN

States and local areas had weaknesses in some public health preparedness elements, including the disease surveillance and laboratory systems and the response capacity of the workforce. Gaps in capacity often are not amenable to solution in the short term because either they require additional resources or the solution takes time to implement. States and local areas were addressing gaps in communication.

SURVEILLANCE SYSTEMS

State and local officials for the cities we visited in early 2002 recognized and were attempting to address inadequacies in their surveillance systems. Local officials were concerned that their surveillance systems were inadequate to detect a bioterrorist event, and all of the states we visited were making efforts to improve their disease surveillance systems. Six of the cities we visited used a passive surveillance system[6] to detect infectious disease outbreaks.[7] However, passive systems may be inadequate to identify a rapidly spreading outbreak in its earliest and most manageable stage because, as officials in three states noted, there is chronic underreporting and a time lag between diagnosis of a condition and the health department's receipt of the report. To improve disease surveillance, six of the states and two of the cities we visited were developing surveillance systems using electronic databases. Several cities were also evaluating the use of nontraditional data sources, such as pharmacy sales, to conduct surveillance.[8] Three of the cities we visited were attempting to improve their surveillance capabilities by incorporating active surveillance components into their systems. For our ongoing work, state and local officials told us that their surveillance systems had improved somewhat. The officials reported that CDC funds have enabled them make some of these improvements in their surveillance systems, including the development of Web-based disease reporting and active surveillance systems.

LABORATORY FACILITIES

Officials from all of the states we visited in early 2002 reported problems with their public health laboratory systems and said that they needed to be upgraded. All states were planning to purchase the equipment necessary for rapidly identifying a biological agent. State and local officials in most of the areas that we visited told us that the public health laboratory systems in their states were stressed, in some cases severely, by the sudden and significant increases in workload during the anthrax incidents in the fall of 2001. During these incidents, the demand for laboratory testing was significant even in states where no anthrax was found and affected the ability of the laboratories to perform their routine public health functions. Following the incidents, over 70,000 suspected anthrax samples were tested in laboratories across the country. According to preliminary data from our interviews and re-

[6] Passive surveillance systems rely on laboratory and hospital staff, physicians, and other relevant sources to take the initiative to provide data on illnesses to the health department, where officials analyze and interpret the information as it arrives. In contrast, in an active disease surveillance system, public health officials contact sources, such as laboratories, hospitals, and physicians, to obtain information on conditions or diseases in order to identitY cases. Active surveillance can provide more complete detection of disease patterns than a system that is wholly dependent on voluntary reporting.

[7] 0fficials in one city told us that although it had no local disease surveillance, its state maintained a passive disease surveillance system.

[8] This type of active surveillance system in which the public health department obtains information tTom such sources as hospitals and pharmacies and conducts ongoing analysis of the data to search for certain combinations of signs and symptoms, is sometimes referred to as a syndromic surveillance system. A senior HHS official stated that research examining the usefulness of syndromic surveillance needs to continue. See S. Lillibridge, *Disease Surveillance, Bioterrorism, and Homeland Security,* Conference Summary and Proceedings Prepared by the Annapolis Center for Science–Based Public Policy (Annapolis, Md.: U.S. Medicine Institute for Health Studies, Dec. 4, 2001).

view of 2003 progress reports, officials reported that CDC funds enabled them to make improvements to their laboratory infrastructure, including upgrading their laboratory facilities, purchasing reagents and equipment, and improving their capability to test for select biologic agents.

Officials in the states we visited in 2002 were working on other solutions to their laboratory problems. States were examining various ways to manage peak loads, including entering into agreements with other states to provide surge capacity, incorporating clinical laboratories into cooperative laboratory systems, and purchasing new equipment. One state was working to alleviate its laboratory problems by upgrading two local public health laboratories to enable them to process samples of more dangerous pathogens and by establishing agreements with other states to provide backup capacity. Another state reported that it was using the funding from CDC to increase the number of pathogens the state laboratory could diagnose. The state also reported that it has worked to identify laboratories in adjacent states that are capable of being reached within 3 hours over surface roads. In addition, all of the states reported that their laboratory response plans had been revised to cover reporting and sharing laboratory results with local public health and law enforcement agencies.

WORKFORCE

At the time of our early 2002 site visits, shortages in personnel existed in state and local public health departments and laboratories and were difficult to remedy. Officials from state and local health departments told us that staffing shortages were a major concern. Two of the states and cities that we visited were particularly concerned that they did not have enough epidemiologists to do the appropriate investigations in an emergency. Officials at one state department of public health we visited said that the department had lost approximately one-third of its staff because of budget cuts over the past decade. This department had been attempting to hire more epidemiologists. Barriers to finding and hiring epidemiologists included noncompetitive salaries and a general shortage of people with the necessary skills.

Workforce capacity issues may also hinder implementation of infectious disease control measures. For example, the shortage of epidemiologists could grow worse if, in the event of a severe outbreak, existing health care workers became infected as a result of their more frequent exposure to a contaminated environment or became exhausted working longer hours. Workforce shortages could be further exacerbated because of the need to conduct contact tracing.[9] According to World Health Organization officials, an individual infected with SARS came in contact with, on average, 30 to 40 people in Asian countries—all of whom had to be contacted and informed of their possible exposure.

During our site visits in early 2002, shortages in laboratory personnel were also cited. Officials in one city noted that they had difficulty filling and maintaining laboratory positions and that people that accepted the positions often left the health department for better-paying positions. Increased funding for hiring staff cannot necessarily solve these shortages in the near term because for many types of laboratory positions there are not enough trained individuals in the workforce. According to the Association of Public Health Laboratories, training laboratory personnel to provide them with the necessary skills will take time and require a strategy for building the needed workforce.[10] For our current work updating these findings, many of the state and local officials we interviewed cited shortages in trained epidemiologists or laboratory personnel as persistent.

In 2002, state and local officials told us that sustained funding would be necessary to address one important need-hiring and retaining needed staff. They told us they would be reluctant to hire additional staff unless they were confident that the funding would be sustained and staff could be retained. These statements are consistent with the findings of the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, which recommended that federal support for state and local public health preparedness and infrastructure building be sustained at an annual rate of $1 billion for the next 5 years to have a material impact on state and local governments' preparedness for

[9] Contact tracing is the identification and tracking of individuals who may have been exposed to a person with a specific disease.

[10] Association of Public Health Laboratories, "State Public Health Laboratory Bioterrorism Capacity," *Public Health Laboratory Issues in Brief Bioterrorism Capacity* (Washington, D.C.: October 2002).

a bioterrorist event.[11] We have noted previously that federal, state, and local governments have a shared responsibility in preparing for terrorist attacks and other disasters.[12] However, prior to the infusion of federal funds, few states were investing in their public health infrastructure.

COMMUNICATION

We found that officials were beginning to address communication problems. For example, six of the seven cities we visited in early 2002 were examining how communication would take place in a public health emergency. Many cities had purchased communication systems that allow officials from different organizations to communicate with one another in real time. In addition, state and local health agencies were working with CDC to build the Health Alert Network (RAN), an information and communication system. The nationwide RAN program has provided funding to establish infrastructure at the local level to improve the collection and transmission of information related to public health preparedness. Goals of the RAN program include providing high-speed Internet connectivity, broadcast capacity for emergency communication, and distancelearning infrastructure for training. For our current work, our preliminary review of the 2003 progress reports from 12 jurisdictions shows that 11 reported that over 90 percent of their population was covered by HAN.

SOME STATE AND LOCAL CONTINGENCY PLANNING UNDERWAY, BUT REGIONAL COORDINATION IS LACKING

As part of the effort to prepare for a possible outbreak of an infectious disease, there is contingency planning at the state and local levels. Health departments, for instance, are in the process of developing contingency response plans for SARS. The SARS preparations have been modeled after a checklist designed for pandemic influenza. To facilitate these preparations, the Association of State and Territorial Health Officials and the National Association of County and City Health Officials, in collaboration with CDC, published a checklist for state and local health officials to use in the event of a SARS resurgence. The checklist encompasses a broad spectrum of preparedness activities, such as legal issues related to isolation and quarantine, strategies for communicating information to health care providers, and suggestions for ensuring other community partners such as law enforcement and school officials are prepared.

During our 2002 site visits, however, we found that response organization officials were concerned about a lack of planning for regional coordination between states during an infectious disease outbreak. As called for by the guidance for the CDC and HRSA funding, all of the states we visited in 2002 organized their planning on the basis of regions within their states, assigning local areas to particular regions for planning purposes. A concern for response organization officials was the lack of planning for regional coordination between states. A hospital official in one city we visited said that state lines presented a "real wall" for planning purposes. Hospital officials in one state reported that they had no agreements with other states to share physicians. However, one local official reported that he had been discussing these issues and had drafted mutual aid agreements for hospitals and emergency medical services. Public health officials from several states reported developing working relationships with officials from other states to provide backup laboratory capacity.

HOSPITAL PREPAREDNESS IMPROVED, BUT LIMITATIONS IN RESPONSE CAPACITY REMAIN

Because those with symptoms of an infectious disease might go to emergency departments for treatment, hospital personnel would likely be some of the first health care workers with the opportunity to identiry an emerging infectious disease out-

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[11] Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, *Fourth Annual Report to the President and the Congress of the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction* (Arlington, Va.: RAND, Dec. 15,2002). The Advisory Panel was established to assess federal agency efforts to enhance domestic preparedness, the progress of federal training programs for local emergency responses, and deficiencies in federal programs for response to incidents involving weapons of mass destruction; to recommend strategies for ensuring effective coordination of federal agency response efforts and for ensuring fully effective local response capabilities for weapons of mass destruction incidents; and to assess appropriate state and local roles in funding effective local response capabilities. The Advisory Panel issues annual reports to the President and to the Congress and has submitted four annuals reports to date.

[12] See U.S. General Accounting Office, *Homeland Security: Effective Intergovernmental Coordination Is Key to Success,* GAO–02–1013T (Washington, D.C.: Aug. 23,2002).

break. Therefore, the disease surveillance capacities of many state and local public health systems may depend, in part, on the surveillance capabilities of hospitals. Most hospitals reported training their staff and planning coordination efforts with other public health entities. However, even with these preparations in place, hospitals lacked the capacity to respond to large-scale infectious disease outbreaks.

HOSPITALS PROVIDE VITAL DISEASE SURVEILLANCE CAPACITY

The disease surveillance capacities of many state and local public health systems may depend, in part, on the surveillance capabilities of hospitals. During the recent SARS outbreak in North America, for instance, hospital emergency rooms played an important role in identirying those who had the disease. According to hospital officials in California and New York, hospital emergency room or other waiting room staff routinely used questiomaires to screen incoming patients for fever, cough, and travel to a country with active cases of SARS. They said that hospitals' signs in various locations generally used by incoming patients and visitors also asked individuals to identiry themselves to hospital staff if they met these criteria. In Toronto, which experienced a much greater prevalence of SARS than the United States, everyone entering a hospital was required to answer screening questions and to have their temperature checked before they were allowed to enter.

MOST HOSPITALS REPORTED PLANNING AND TRAINING EFFORTS, BUT FEWER THAN HALF HAVE PARTICIPATED IN DRILLS OR EXERCISES

In our survey of over 2,000 metropolitan hospitals,[13] most reported that they have provided training to staff on biological agents, but fewer than half have participated in drills or exercises related to bioterrorism. Most hospitals we surveyed reported providing training about identifying and diagnosing symptoms for the six biological agents identified by the CDC as most likely to be used in a bioterrorist attack. At least 90 percent of hospitals reported providing training for two of these agents—smallpox and anthrax-and approximately three-fourths of hospitals reported providing training about the other four—plague, botulism, tularemia, and hemorrhagic fever viruses.

Our hospital survey found that 4 out of 5 hospitals reported having a written emergency response plan for large-scale infectious disease outbreaks. Of the hospitals with emergency response plans, most include a description of how to achieve surge capacity for obtaining additional pharmaceuticals, other supplies, and staff. In addition, almost all hospitals reported participating in community interagency disaster preparedness committees.

At the time of our site visits between December 2001 and March 2002, we found that hospitals were beginning to coordinate with other local response organizations and collaborate with each other in local planning efforts. Hospital officials in one city we visited told us that until September 11,2001, hospitals were not seen as part of a response to a terrorist event but that city officials had come to realize that the first responders to a bioterrorism incident could be a hospital's medical staff. Officials from the state began to emphasize the need for a local approach to hospital preparedness. They said, however, that it was difficult to impress the importance of cooperation on hospitals because hospitals had not seen themselves as part of a local response system. The local government officials were asking them to create plans that integrated the city's hospitals and addressed such issues as off-site triage of patients and off-site acute care.

MOST EMERGENCY DEPARTMENTS HAVE EXPERIENCED SOME DEGREE OF CROWDING

Our survey of metropolitan hospitals found that most emergency departments have experienced some degree of overcrowding.[14] Persons with symptoms of infectious disease would potentially go to emergency departments for treatment, further stressing these facilities. The problem of overcrowding is much more pronounced in some hospitals and areas than in others. In general, hospitals that reported the most problems with crowding were in the largest metropolitan statistical areas (MSA) and in the MSAs with high population growth. For example, in fiscal year 2001, hospitals in MSAs with populations of 2.5 million or more had about 162

[13] Between May and September 2002, we surveyed over 2,000 short-term, nonfederal general medical and surgical hospitals with emergency departments located in metropolitan statistical areas. (See U.S. General Accounting Office, *Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities,* GAO–03–460 (Washington, D.C.: Mar. 14,2003) for information on the survey universe and development ofthe survey.) For the part of the survey that specificaIly addressed hospital preparedness for mass casualty incidents, we obtained responses from 1,482 hospitals, a response rate of about 73 percent.

[14] GAO–03–460.

hours of diversion (an indicator of crowding),[15] compared with about 9 hours for hospitals in MSAs with populations of less than 1 million. Also, the median number of hours of diversion in fiscal year 2001 for hospitals in MSAs with a high percentage population growth was about five times that for hospitals in MSAs with lower percentage population growth.

Hospitals in the largest MSAs and in MSAs with high population growth that have reported crowding in emergency departments may have difficulty handling a large influx of patients during a potential infectious disease outbreak, especially if this outbreak occurred in the winter months when the incidence of influenza is quite high. For example, public health officials with whom we spoke said that in the event of a large-scale SARS outbreak, entire hospital wards may need to be used as separate SARS isolation facilities. Moreover, certain hospitals within a community may need to be designated as SARS hospitals.

Concluding Observations

Efforts at the state and local level have improved the ability to identify and respond to infectious disease outbreaks and bioterrorism. These improvements have included upgrades to laboratory facilities and communication systems. Hospitals have also begun planning and training efforts to respond to large-scale infectious disease outbreaks. Despite these improvements, gaps in preparedness remain. We found that some disease surveillance systems may be inadequate, that there are shortages of key personnel in some localities, and that some hospital emergency departments across the country have experienced some degree of overcrowding which could be exacerbated during a disease outbreak.

Mr. Chairman, this completes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have at this time.

Contact and Staff Acknowledgments

For further information about this testimony, please contact Janet Heinrich at (202) 512–7119. Angela Choy, Krister Friday, Martin T. Gahart, Gay Hee Lee, and Deborah Miller also made key contributions to this statement.

RELATED GAO PRODUCTS

Hospital Preparedness: Most Urban Hospitals Have Emergency Plans but Lack Certain Capacities for Bioterrorism Response. GAO–03–924. Washington, D.C.: August 6,2003.

Severe Acute Respiratory Syndrome: Established Infectious Disease Control Measures Helped Contain Spread, But a Large–Scale Resurgence May Pose Challenges. GAO–03–1058T. Washington, D.C.: July 30, 2003.

Bioterrorism: Information Technology Strategy Could Strengthen Federal Agencies' Abilities to Respond to Public Health Emergencies. GAO–03–139. Washington, D.C.: May 30, 2003.

SARS Outbreak: Improvements to Public Health Capacity are Neededfor Responding to Bioterrorism and Emerging Infectious Diseases. GAO–03–769T. Washington, D.C.: May 7, 2003.

Smallpox Vaccination: Implementation of National Program Faces Challenges. GAO–03–578. Washington, D.C.: April 30, 2003.

Infectious Disease Outbreaks: Bioterrorism Preparedness Efforts Have Improved Public Health Response Capacity, but Gaps Remain. GAO–03–654T. Washington, D.C.: April 9,2003.

Bioterrorism: Preparedness Varied across State and Local Jurisdictions. GAO03–373. Washington, D.C.: April 7, 2003.

Hospital Emergency Departments: Crowded Conditions Vary among Hospitals and Communities. GAO–03–460. Washington, D.C.: March 14, 2003.

Homeland Security: New Department Could Improve Coordination but Transferring Control of Certain Public Health Programs Raises Concerns. GAO–02–954T. Washington, D.C.: July 16,2002.

Homeland Security: New Department Could Improve Biomedical R&D Coordination but May Disrupt Dual–Purpose Efforts. GAO–02–924T. Washington, D.C.: July 9, 2002.

Homeland Security: New Department Could Improve Coordination but May Complicate Priority Setting. GAO–02–893T. Washington, D.C.:

Homeland Security: New Department Could Improve Coordination but May Complicate Public Health Priority Setting. GAO–02–883T. Washington, D.C.: June 25, 2002.

[15] Diversions occur when hospitals request that en route ambulances bypass their emergency departments and transport patients that would have otherwise been taken to those emergency departments to other medical facilities.

Bioterrorism: The Centers for Disease Control and Prevention's Role in Public Health Protection. GAO–02–235T. Washington, D.C.: November 15,2001.
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West Nile Virus Outbreak: Lessons for Public Health Preparedness. GAO/HEHS–00–180. Washington, D.C.: September 11,2000.
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Combating Terrorism: Observations on Biological Terrorism and Public Health Initiatives. GAO/T–NSIAD–99–112. Washington, D.C.: March 16, 1999.

September 24, 2003

INFECTIOUS DISEASES

Gaps Remain in Surveillance Capabilities of State and Local Agencies

What GAO Found

The efforts of public health agencies and health care organizations to increase their preparedness for infectious disease outbreaks and bioterrorism have improved the nation's ability to recognize such events. However, gaps remain in state and local disease surveillance systems, which are essential to public health efforts to respond to disease outbreaks or bioterrorist attacks. Other essential elements of preparedness include laboratory facilities, workforce, and communication systems. State and local officials report that they are addressing gaps in communication systems. However, there are still significant workforce shortages in state and local health departments and laboratories. GAO also found that while contingency plans are being developed at the state and local levels, planning for regional coordination for disease outbreaks or bioterrorist events was lacking between states.

The disease surveillance capacities of many state and local pubic health systems depend, in part, on the surveillance capabilities of hospitals. Whether a disease outbreak occurs naturally or due to the intentional release of a harmful biological agent by a terrorist, much of the initial response would occur at the local level, particularly at hospitals and their emergency departments. Therefore, hospital personnel would be some of the first healthcare workers with the opportunity to identify an infectious disease outbreak or a bioterrorist event. Most hospitals reported training their staff on biological agents and planning coordination efforts with public health entities; however, preparedness limitations may impact hospitals' ability to conduct disease surveillance. In addition, hospitals still lack the capacity to respond to large-scale infectious disease outbreaks. Also, most emergency departments across the country have experienced some degree of overcrowding, which could be exacerbated during a disease outbreak or bioterrorist event if persons with symptoms go to emergency departments for treatment.

Mr. SHADEGG. Thank you, Ms. Heinrich.

Next we will hear from Dr. Richard Platt, Chair, Department of Ambulatory Care and Prevention, Harvard Pilgrim Health Care. Dr. Platt?

STATEMENT OF DR. RICHARD PLATT, CHAIR OF THE AMBULATORY CARE AND PREVENTION, HARVARD HEALTH PLAN

Dr. PLATT. Thank you, Mr. Chairman and members of the committee.

I should also say that although I am a professor at Harvard Medical School, my medical school department is jointly sponsored by a health plan, Harvard Pilgrim Health Care. I appreciate the opportunity to talk with you today about the CDC-sponsored National Bioterrorism Surveillance Demonstration Program that my partners and I are undertaking. This is a three-way partnership that involves the health plans, the public health sector and the academic community.

The health plans bring to this partnership their rich information sources and ability to communicate with large numbers of clinicians and their patients. The public health sector brings the ability to set priorities and coordinate responses. The academic community is contributing its information and knowledge and tools.

This partnership has been active for some time and has been working on a number of important health problems, including bioterrorism preparedness. My own experience in detecting bioterrorism began in 2000 with a grant from the CDC to the Massachusetts Department of Public Health. I should point out that was before 9–11. We use information from the electronic medical records of a large physician group to gather diagnoses as soon as they are made, and then we analyze this information for evidence of unusual disease activity and we communicate that back to our public health colleagues.

You have handouts at your desk showing an example of the kind of information we give to our pubic health colleagues. This is a screen shot of our protected Web site showing the disease activity in the Greater Boston area yesterday. This information became available early this morning. It shows that nothing unusual happened yesterday. The way it does that is to highlight the five most unusual census tracts in the Greater Boston area. In this way, our public health colleagues do not have to evaluate a lot of numbers. They have to look at what is unusual, and we get to this unusualness by taking into account the number of health plan members who live in those census tracts and the number of other factors that affect disease incidence.

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Bioterrorism Surveillance

Boston Bioterrorism Surveillance Daily Reports

Monday, 22 September, 2003 <Prev | Up to Dates | (No future report available yet)

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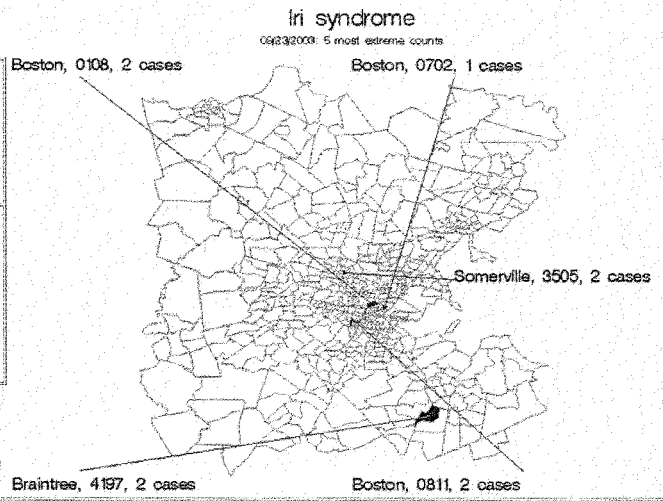
lri syndrome by census tract
Tuesday, 23 September 2003
Tracts with most extreme counts compared to their own history.*

Town or City	Census tract code	Cases in tract	Denominator in this tract	Number of years between counts this extreme^
Somerville	250173505	2	252	0
Boston	250250811	2	308	0
Boston	250250108	2	488	0
Braintree	250214197	2	415	0
Boston	250250702	1	121	0

* The 5 most extreme tracts are shown, plus all with counts not expected to occur more than once per month.
^ Estimated number of years between daily counts this extreme in



Internet

This information provides early warning for both bioterrorism and naturally occurring illnesses. The system is also flexible enough to add additional purposes that we had not originally planned. For instance, soon after we activated this system, the State's influenza tracking branch asked us to track influenza-like illness and we added that at no cost to the system or to our sponsors, and report that on a regular basis now. We are currently in discussions about ways that we might monitor SARS if it appears in our community.

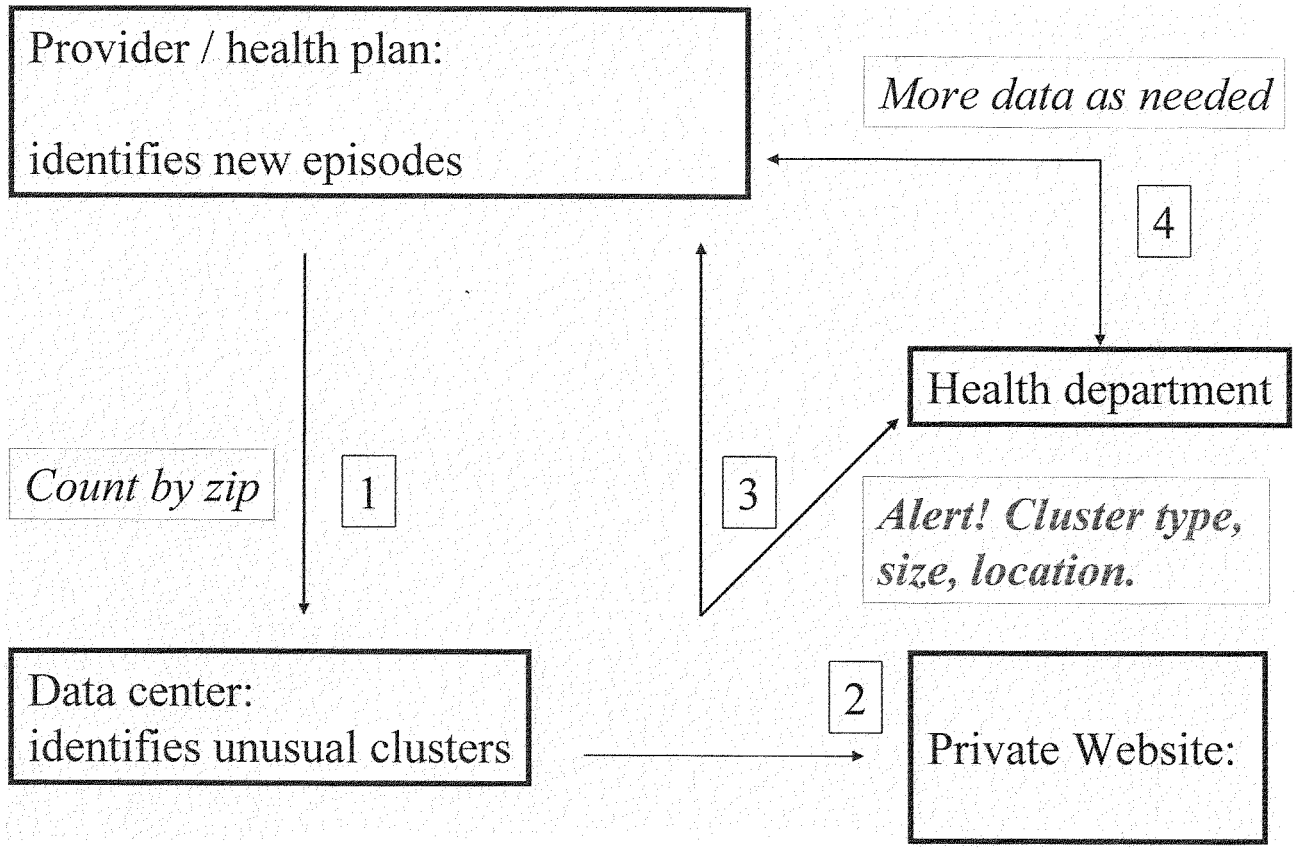
I believe that three major elements contribute to the success of our program. The first is the availability of electronic medical records. They are complete, they are available immediately, and the process of obtaining information does not require the clinicians to take any additional actions beyond the regular care they deliver.

The second important element was the development of a computerized method to identify potential outbreaks. The system takes into account historical patterns of illness and allows us to recognize unusual numbers of events as early as possible. This is important because recognizing an outbreak can be like viewing a mosaic while standing very close to it. At least initially, the key may be the pattern of cases, rather than the features of any individual case, and these patterns can differ at different times and in different places, and therefore be difficult to recognize early. Using computerized identification methods also allows us to provide alerts to public health officials so they do not have to examine the actual numbers of illnesses each day, especially when there is no special concern.

The third element of our success was the willingness of the health plan and the physicians to share their medical record information. The major reason for this is that we designed the system so that they continue to be the custodians of their patients's healthcare data. All that they provide to us is the number of new cases of different kinds of illness in each area. If we detect a potential cluster, then the health department requests information from the health plan about the specific cases that contribute to that cluster. We built a mechanism to allow them to obtain that additional information very quickly. This arrangement corresponds to the health plan's and clinician's understanding of their patients's strong desire that information about their individual medical visits be kept private unless there is an immediate and compelling public health need for it.

During the past year, the CDC has supported our work to create a system that uses these principles to integrate information from many health plans. Our principal partner in this activity is the American Association of Health Plans, which represents approximately 1,000 health plans that care for over 170 million Americans. Additional participants include health plans in Minnesota, Massachusetts, Colorado and Texas, and the National Nurse Call Center that cares for individuals in all 50 States.

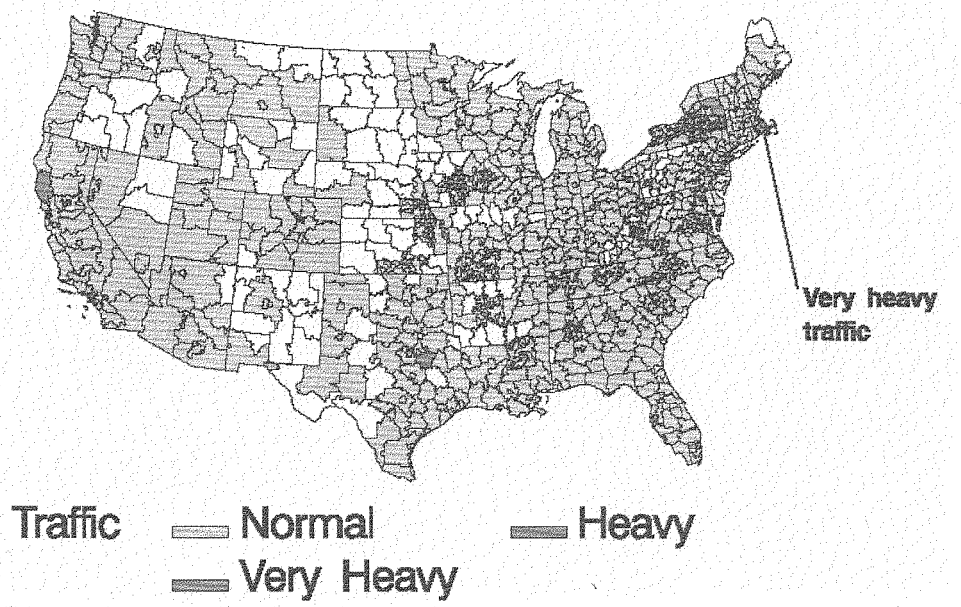
The information on the second page of your handout shows the data flow for this system, with health plans identifying new episodes, communicating that to the data center using protected Internet technology. The data center uses that count information to identify unusual clusters. The information is posted on a protected Web site. When there is a cluster, we can notify both the health plan and the health department. The health plan and the health department then interact with each other to further their communication. Although we are still creating some parts of this system, our preliminary evidence indicates that it does identify outbreaks of public health interest.


Provider / health plan:
identifies new episodes
More data as needed
4
Health department
Count by zip
1
3
Alert! Cluster type, size, location.
Data center:
identifies unusual clusters
2
Private Website:

If you take a look at the third sheet of the handout, this is a national map showing the disease incidence in the middle of last December. I picked this date because although most of the nation, which is colored pink, is showing that there is no unusual data, in Massachusetts there is quite an impressive spike. It is hard to see on this sheet, but if you look at the next page it shows that in Massachusetts you can see that there are a number of zip codes in Massachusetts that have an unusually high volume of new respiratory illnesses. By our calculations, this was a once in 8-year event that lasted 4 days and involved hundreds of people.

48 States surveillance: 12/16/2002

Respiratory Complaints



We have several goals for the coming year. First, we want to make the transition to a stable, ongoing system. In addition, we are in discussion with our colleagues at the CDC about ways that we can collaborate with Project BioSense to adapt our detection methods to that system and to make the data from our health plans available through BioSense. We also want to work with CDC to improve health departments's ability to communicate quickly and effectively with practicing clinicians and the millions of individuals for whom they provide care. We also hope to make use of new types of medical information and to develop more sophisticated methods for developing disease outbreaks at the earliest possible time.

In summary, we have learned that routinely collected health plan data can be an important public health resource and it can be used in ways that minimizes patients's privacy concerns. My colleagues and I believe that this system can make a valuable contribution to the public health system's ability to identify and to respond to health threats at the earliest possible moment.

I also believe that our work is even more important as an example of the possibilities of the partnerships that we can create between the private healthcare delivery system, the public health sector, and the academic community. Because of this, I believe that this three-way partnership has the potential to transform the health of our society if we take the proper steps to nurture it.

Thank you very much.

[The statement of Dr. Platt follows:]

PREPARED STATEMENT OF RICHARD PLATT

Good afternoon Mr. Chairman and members of the Subcommittee. My name is Richard Platt; I am a Professor at Harvard Medical School, where I chair the Department of Ambulatory Care and Prevention, a department that is unique in being jointly sponsored by a medical school and by a health plan, Harvard Pilgrim Health Care. I am also an infectious diseases specialist, an epidemiologist, and a member of the Board of Scientific Counselors of the Center for Disease Control and Prevention's (CDC) National Center for Infectious Diseases.

I am very excited about this opportunity to discuss our National Bioterrorism Surveillance Demonstration Program and the work we do daily to detect and respond to both bioterrorism and naturally occurring disease outbreaks. The National Demonstration Program is the product of an evolving three-way partnership between private health plans and physician groups, public health agencies, and the academic community. This partnership makes an important contribution to protecting the overall health of our nation by combining our unique strengths:

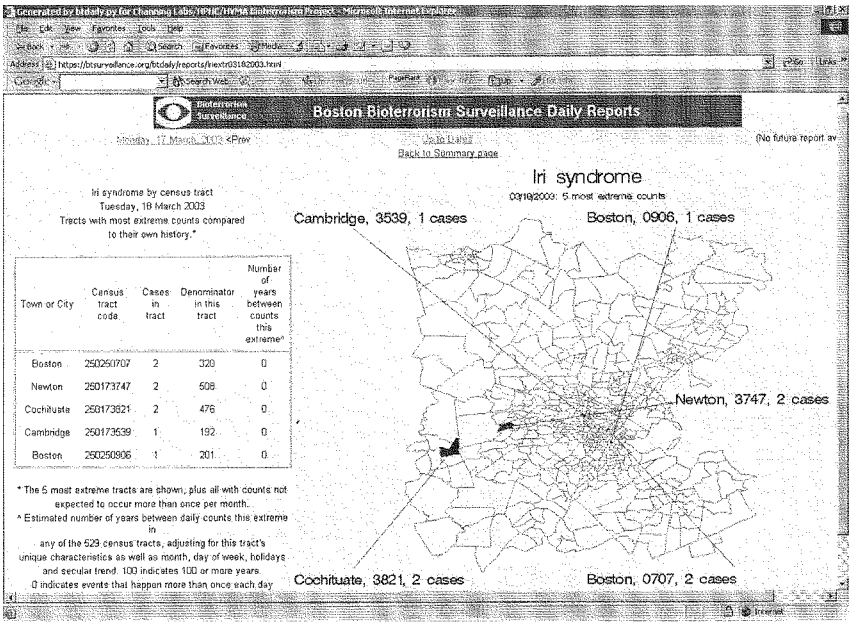
- the private health system's information infrastructure and its ability to communicate both with clinicians and with the people for whom they provide care;
- the public sector's ability to set major health priorities and coordinate a response; and
- the academic community's skills in developing the knowledge and tools to make the most of these capabilities.

In addition to the work I will describe today, this three-way partnership is currently making important contributions to our ability to prevent illness, treat disease, improve the safety of drugs and vaccines, and improve the delivery of health care.

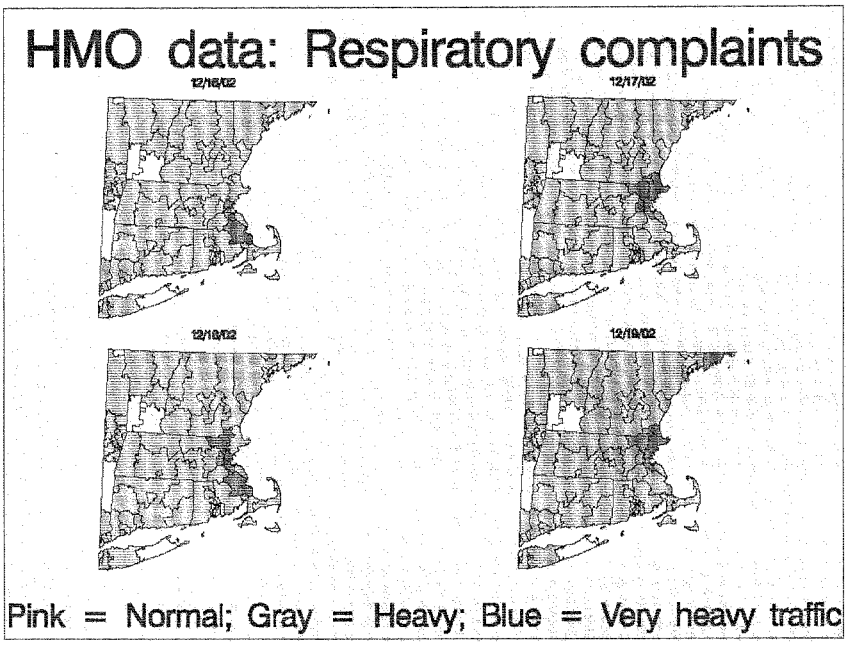
Before I describe our National Demonstration Program, I think it will be helpful for you to know how it began. My work on detecting bioterrorism began in 2000 when the Massachusetts State Epidemiologist, Dr. Alfred DeMaria, and I developed a partnership between the Massachusetts Department of Public Health, Harvard Pilgrim Health Care, and Harvard Vanguard Medical Associates to enhance early-detection and public health communication capabilities. This project was supported by a bioterrorism preparedness grant from the CDC to the State of Massachusetts. We had three major goals: first to quickly gather the diagnoses made in everyday practice by hundreds of physicians in eastern Massachusetts; then to analyze this information for evidence of unusual disease activity; and finally to create a mecha-

nism for public health officials to communicate rapidly with clinicians to follow up the outbreak signals we detected. Because of our early start, our eastern Massachusetts detection system went "live" in October of 2001, within weeks of the anthrax attack that brought bioterrorism to prominence. This system is described in articles in Emerging Infectious Diseases (2002 Aug;8(8):753–60) and BMC Public Health (2001;1:9).

Our system has been active since then, identifying the census tracts in our region with the most unusual number of new cases of respiratory, gastrointestinal, and several other categories of illness, which may indicate potential outbreaks. This information is displayed via maps and tables on a secure internet site that is accessible to the state health department. The following illustration shows the information that public health officials view on a typical day.


Boston Bioterrorism Surveillance Daily Reports
Back to Summary page
Iri syndrome
03/19/2003: 5 most extreme counts
Iri syndrome by census tract
Tuesday, 18 March 2003
Tracts with most extreme counts compared
to their own history.*
Town or City | Census tract code | Cases in tract | Denominator in this tract | Number of years between counts this extreme^
Boston | 250250707 | 2 | 320 | 0
Newton | 250173747 | 2 | 508 | 0
Cochituate | 250173821 | 2 | 476 | 0
Cambridge | 250173539 | 1 | 192 | 0
Boston | 250250906 | 1 | 201 | 0
* The 5 most extreme tracts are shown, plus all with counts not expected to occur more than once per month.
^ Estimated number of years between daily counts this extreme in any of the 529 census tracts, adjusting for this tract's unique characteristics as well as month, day of week, holidays and secular trend. 100 indicates 100 or more years. 0 indicates events that happen more than once each day
Cambridge, 3539, 1 cases
Boston, 0906, 1 cases
Newton, 3747, 2 cases
Cochituate, 3821, 2 cases
Boston, 0707, 2 cases

An important feature of this display is that it only highlights areas with the most unusual number of people who have a new episode of illness, after eliminating seasonal and other effects. On the majority of days, nothing unusual occurs. However, when we observe an unusually large number of cases in a specific locale, a clinician who works in the medical practice that provides the information, and who is responsible for public health reporting, provides additional information to the health department. Fortunately, there have been no cases of bioterrorism since our program became active. However, we understood from the outset that this information would also serve a separate purpose of providing routine, high quality, timely, information to the public health department about naturally occurring illnesses in these communities—earlier than is possible with traditional physician reporting of diagnosed diseases. Using historical data from the health plan and state records, we were able to demonstrate that office visits for wintertime respiratory illness increased about two weeks before an increase in respiratory hospitalizations occurred. In addition, we have been able to identify unusual clusters of respiratory infections, as shown in the following figure, which illustrates a once-in-eight-year cluster involving hundreds of people that occurred last December.


HMO data: Respiratory complaints
12/16/02
12/17/02
12/18/02
12/19/02
Pink = Normal; Gray = Heavy; Blue = Very heavy traffic

Soon after we began providing routine reports to our colleagues in the Massachusetts Department of Health, the department's influenza tracking branch requested that we report a new disease category—*influenza-like illness*— and we added this feature without any additional resources from the clinical system or the state. We are currently discussing with CDC ways to adapt this system to detect the occurrence of Severe Acute Respiratory Syndrome (SARS) if it appears in our region. The Institute of Medicine (10M) described this detection system in Massachusetts as an example of the ability of the health care delivery system to play an important role in disease detection and reporting in its recent report, "The Future of the Public's Health in the 21st Century," (page 249).

Several critical elements contribute to the success of this program. The first is the fact that a large physician group, Harvard Vanguard Medical Associates, uses electronic medical records to provide routine patient care. Therefore, information about diagnoses, symptoms, and vital signs is available at the end of each day. Clinicians are not required to collect any additional information, to record it in any special way, or to take any additional steps to report needed information. Thus, we avoid burdening already overloaded clinicians and their support staff and we are confident that the clinical information is complete. In addition, since we focus on health plan members, we also know how many members are not sick. This provides added confidence that the detection system will alert us to problems that occur in the health plans' enrolled population.

The second important element was development of a method to identify potential outbreaks. We accomplish this using a computerized analysis program that takes into account historical patterns of illness and allows us to recognize when unusual numbers of events occur. Assessing patterns of illness is important because our system looks for clusters of individual cases that may not seem unusual to the clinicians who are providing care. The absence of distinguishing features is often the case for conditions like SARS. It causes severe symptoms in only a small fraction of infected people, yet detection of the larger number of people who develop mild symptoms and then recover may signal the arrival of the virus to an area. Additionally, even life-threatening illnesses like anthrax and smallpox typically begin with a few days of mild illness that cannot be distinguished in routine practice from common illnesses. Even highly experienced epidemiologists find it difficult to recognize unusual numbers of illnesses because of the difficulty of taking into account multiple factors—the day of the week, the season, whether it is the day after a holiday, the history of incidence over prior years, and the typical patterns of care in specific communities. An unusually high number of ill people on a Wednesday in August may be quite ordinary for a Monday in January, and a few cases in one community can be much more significant than a much larger number in a nearby community. Thus, our cluster detection analysis system is a key element in the system's effectiveness.

An additional reason to use computerized methods to identify unusual situations is to provide alerts to public health officials. Our public health colleagues have advised us that it is inefficient to examine the actual numbers of illnesses each day, especially when there is no special concern. In short, our detection system sifts and analyzes huge volumes of data and only in rare cases alerts public health officials to an unusual signal that requires attention.

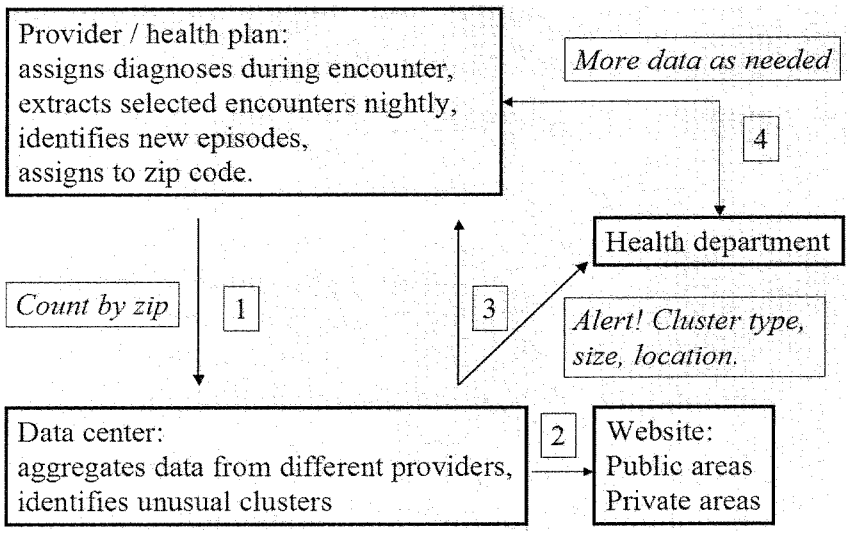
A third important contributor to our success is the willingness of the health plan and physicians' practice to share this critical health information. One reason health plans and medical groups are willing to do this is that we constructed the system so that they continue to be custodians of their patients' health care data, providing only the information that is needed for tracking the public's health. The only information that health plans submit to us is the number of individuals in each zip code or census tract with visits for respiratory, gastrointestinal, or other types of medical problems. If the number of cases is unusually large, the health department requests the corresponding visit-by visit information, which is stored at the health plan. The health department contacts a designated clinical responder in the health plan for any additional information that is needed. The clinician responds in a timely manner and has ready access to information about the individual and the details of the illness.

Organizing the system this way is appealing to the health plans and the public for two major reasons. First, it corresponds to the public's desire for health plans and physicians to keep information about their individual medical visits private unless there is a compelling public health need for such information. Second, health plans know that visit level information can be used for other purposes, such as litigation and competitive purposes, and so they want to be as certain as possible that the information they provide is accurate and used only for the intended purpose—public health. Several health plans have had recent experiences in which a public health agency has not been able to assure the confidentiality of data that they provided. While many health plans believe strongly in contributing actively to our nation's public health, they also want to minimize the possibility that doing so will breach confidentiality.

During the past year, we have developed the capacity to integrate real-time bioterrorism and disease detection information from many health plans. This National Demonstration Program has been supported by the CDC through a grant to one of its Prevention Epicenters, which I lead. The design of this program has been guided by our work in Massachusetts, as well as the considerable experience of health plans in Minnesota and Colorado. Our major partner in this work is the American Association of Health Plans, which is the principal national organization representing more than 1,000 health plans that provide coverage for more than 170 million Americans nationwide. Additional participants are four health plans or physician groups—Harvard Pilgrim Health Care/Harvard Vanguard Medical Associates (Massachusetts), HealthPartners (Minnesota), Kaiser Permanente Colorado, and UnitedHealthcare's nurse call center, Optum. The coordinating center is at Harvard Medical School's Channing Laboratory.

We also recently began working with three health providers in Texas, Scott and White Healthcare System, the Austin Regional Clinic, and Austin Diagnostic Clinic, after a local health officer asked us to help him develop a disease surveillance system. The health officer secured necessary funding from the Texas Association of Local Health Organizations to support their participation. All of our health plan partners have some form of electronic health information. Detailed information about this program has been described in articles in the Journal of Urban Health (2003;80 #2, Supplement l:i25–i31) and the National Journal (April 19, 2003, p 1238–9).

We are making excellent progress and are enthusiastic about the prospects of this detection program. We have created computer programs that allow the health plans to automate the large majority of their activities. These programs analyze daily clinical information and group together visits with different diagnoses, for instance "cough" and "bronchitis", identify new episodes of illness so that repeat visits for the same illness are not counted twice, assign the new episodes to the zip codes where the patients live, count the number of new episodes in each zip code, and then transmit only this summary information automatically over a secure internet connection to the coordinating center at Harvard. At the coordinating center, we combine the information from different health plans and search for unusual patterns of illness. The computer programs we have developed for the health plans also maintain detailed lists of the clinical information that underlies the numbers provided to the coordinating center. These detailed lists are kept by the health plan and are immediately accessible to the clinical responders when a public health department seeks additional information for investigation of a possible outbreak. The information flow is shown in the following diagram.


Provider / health plan:
assigns diagnoses during encounter,
extracts selected encounters nightly,
identifies new episodes,
assigns to zip code.
More data as needed
4
Health department
Count by zip
1
3
Alert! Cluster type, size, location.
Data center:
aggregates data from different providers,
identifies unusual clusters
2
Website:
Public areas
Private areas

We are currently working with our state and local health department partners to evaluate our surveillance system's capabilities by comparing the clusters that we identify through health plan data to confirmed past outbreaks that health departments have detected through their usual method of identification. Our preliminary comparison indicates that our system identifies the large majority of recognized outbreaks that occurred during the past two years, and it also highlights potential clusters that the public health system may not have detected.

We are also developing the ability to notify health departments automatically of clusters that they wish to know about, through pagers or e-mail. We expect this will be the most efficient method of ensuring that needed information is used by public health agencies at the earliest possible opportunity. At present, we are waiting for the public health departments to provide the specifications for these automatic notifications.

In all of our activities, we try to use definitions and methods that are consistent with evolving public health practice, with the goal of making our information compatible with other detection and response systems, including the ESSENCE system developed by the Department of Defense, and the CDC's BioSense initiative. We are currently discussing with CDC the contributions we can make to BioSense, both in adapting our signal detection methods to the broad range of data types in BioSense, and making data from our health plans available to the public health community through BioSense. We look forward to working with CDC and are certain that a continued public-private partnership provides the greatest opportunity for improved homeland security.

We have just been notified that we will receive funding to continue this program beyond its first year. Our goals include making the transition from program development and testing to a stable, ongoing system and collaborating with BioSense, as described above. We especially want to work with CDC to improve public health departments' ability to communicate quickly and effectively with the large majority of practicing clinicians in this country and with over 170 million individuals for whose care the health plans are responsible. We are convinced there is important additional work to do in acquiring new types of data, for instance emergency room visit information, additional information from health plans, and in developing more sophisticated mathematical models that will allow us to do a better job combining information from different data sources within a single health plan (for instance, regular office visits and emergency room visits) and aggregate information from several plans that serve a single area. We are also talking with other health plans and physician groups that are interested in contributing their information to this system. We also look forward to working with our public health partners to creating a wide array of new uses for health plans' data and their ability to communicate with clinicians and the people for whom they provide care. We believe the framework we have created will facilitate this development.

In conclusion, I want to thank you again for the opportunity to discuss our work with you. My colleagues and I believe this system can make a valuable contribution to the public health system's ability to identify and respond to bioterrorism and other emerging threats at the earliest possible moment and it can be expanded to report health plan data nationally. I also believe it is even more important as an example of the partnerships we can create between the private health care delivery system, the public health sector, and the academic community. I believe this three-way partnership has the potential to transform the health of our society during the coming years if we take the right steps to nurture it.

Mr. SHADEGG. Thank you, Doctor.

We will next hear from Dr. Jonathan L. Temte, infectious disease specialist with the American Academy of Family Physicians. Doctor?

STATEMENT OF DR. JONATHAN TEMTE, INFECTIOUS DISEASE SPECIALIST, AMERICAN ACADEMY OF FAMILY PHYSICIANS

Dr. TEMTE. On behalf of the 94,000 members of the American Academy of Family Physicians, I thank Chairman Shadegg and the subcommittee for the opportunity to discuss detection of bioterrorism in primary care. As Mrs. Christensen can probably attest, family doctors like to talk a lot, but I will try and keep my comments within the 5-minute limit.

My goal today is to leave you with these three main themes. First, defense against bioterrorism is dependent upon frontline physicians. Second, surveillance is necessary for bioterrorism, but it is not sufficient. And third, there is a real and growing threat to the integrity of our first line of defense.

The United States needs frontline primary care physicians. Detection of bioterrorism requires that astute clinicians are available whenever and wherever a victim first presents for medical care. On October 2, 2001, an astute clinician made a diagnosis of anthrax. Ten additional cases of inhalational anthrax eventually presented to physicians from multiple specialties in multiple states. In each case, the correct diagnosis was made using usual medical care. In retrospect, no additional cases were discovered.

On May 20, 2003, a 3-year-old girl was brought to her primary care physician for evaluation of a bite wound to her finger. Within 10 days of the initial visit, the diagnosis of an unusual pox virus was made. The CDC confirmed the very first case of monkeypox in the Western Hemisphere. This diagnosis was made using the physicians and facilities in a town of 19,000 people in rural Wisconsin.

In these examples, very rare diseases were detected by astute clinicians doing no more than what they were trained to do on a day-to-day basis. Will physicians immediately recognize illnesses due to bioterrorism? The answer is no. Will the cases of bioterrorism be identified through usual medical care? Here the answer is yes, if those patients have access to well-trained and competent physicians.

Family physicians are widely dispersed across America and see patients regardless of age, gender or affected organ system. It is estimated that family physicians evaluate and manage a total of one billion individual medical problems each year in this country, and can put these problems into context because we know our patients and their families, and we know their communities. Accordingly, in the event of future bioterrorism events, the first cases will likely present to family physicians and other primary care specialists.

Surveillance for bioterrorism events is totally necessary, but it is not sufficient. For surveillance to be workable, it has to be highly sensitive and have extreme timeliness of detection. These two properties, however, come at an extremely high price. When applied to things that are very, very rare, and bioterrorism is rare, surveillance will produce a high rate of false positive alarms and rapidly overwhelm everyone involved.

Surveillance of disease trends, on the other hand, can enhance the role of the astute clinician. Clinicians are better able to evaluate their patients when informed of current trends in infectious diseases. Moreover, established communications systems between public health and primary care physicians that are reliable and relevant can also be used to alert clinicians of new and upcoming threats.

While we are facing some significant threats to our first line of defense, primary care in the United States is declining. Family physicians deal with an ever-increasing number of problems, coupled with less compensation and increased regulation. The number of graduating family physicians peaked in 2000. More telling, the

number of training positions filled with U.S. medical school graduates peaked in 1997 and has been steadily declining ever since.

The message I would like to leave you with today is this. Our nation is blessed with an abundance of well-trained, competent and compassionate physicians. If an act of bioterrorism occurs again, it is highly likely that an astute primary care physician doing what he or she is trained to do, will detect the first case and sound the alarm. Moreover, it is highly likely that that physician and his or her colleagues will not only provide the appropriate treatment to that patient, but educate and reassure the other worried patients that come in, and reduce the panic and terror that is associated with bioterrorism.

Thank you.

[The statement of Dr. Temte follows:]

PREPARED STATEMENT OF DR. JONATHAN L. TEMTE

It is a great honor and privilege to represent the American Academy of Family Physicians and its 94,300 members before the House Select Homeland Security Subcommittee on Emergency Preparedness and Response. We, along with our colleagues in pediatrics, general internal medicine, and other medical specialties represent the first line of defense and the cornerstone of defense against bioterrorism. We are primary care physicians-or a term that I tend to prefer—comprehensive care physicians.

I sit before you today to provide the viewpoint of a practicing family physician on the primary care physician's role in the detection and response to bioterrorism.

Biodefense in Medical Practice

Much of today's real biodefense dates back to 1910—the year that the Flexner Report was published. This report set into motion a system-wide revolution in American medicine. It called for standardization in medical education. Out of the recommendations of the Flexner Report came what we expect and demand today from our physicians: comprehensive and competent medical care. Through the review and accreditation of our four-year medical schools and through the review and accreditation of our post-graduate residency training programs, the American medical system has yielded a wonderful fruit, and that is the realized expectation that medical care is relatively stable across geographic, economic, ethnic and cultural divisions.

That is not to say that disparities do not exist. We all know they do. Nevertheless, I have the greatest confidence that were I to slump over with chest pain here before you and were whisked off to a local medical center, I would receive care similar to that which I would receive at home.

Physicians are trained to interact with people, and once one interacts with people, one faces uncertainty. Medical practice consists of equal parts of science and art. We face uncertainty on a daily basis and are trained to take the complaints and concerns placed before us and make good choices regarding advice and treatment. The core product of an encounter with a patient is the differential diagnosis—that set of diagnostic possibilities that could explain our patient's symptoms and findings. For example, in the case of inhalational anthrax, we have shown that family physicians identify no less than 35 separate and distinct diagnostic categories based on the initial presentation of this disease. Once set, our job is to narrow the diagnosis using clues from our experience, physical examination, the progression of the disorder, laboratory tests, radiographs and other technological tools. Across the nation, physicians approach similar problems in similar ways. The first line of defense against bioterrorism, therefore, is nothing more than the comprehensive, competent, complete and compassionate application of medical knowledge, skill and experience. This has been a given since 1910. Let me provide two examples:

On October 2, 2001, an incoherent, 63-year-old man with a fever presented to a Florida emergency room. Meningitis was a possible diagnosis, and later that day he underwent a spinal tap. An infectious disease specialist examined the resulting fluid, and noted unusual-appearing bacteria. A diagnosis of anthrax was first entertained. Within two days, the Florida Department of Health Laboratory had confirmed anthrax and CDC investigators were conducting epidemiological investigations. On October 5, at the invitation of the American Academy of Family Physicians, I provided a one-hour lecture about agents of biological terrorism to an audience of 2,500 family physicians at the Annual Scientific Assembly. Information

flowed nearly instantaneously onto the Academy's website. In various fashions, similar information flowed out to physicians from all specialties across America. This same day, the patient died. By the following day—October 6—an autopsy confirmed a diagnosis of inhalational anthrax. . . and the dawn of modem bioterrorism.

Within the course of four days, the cause of a patient's illness was fully diagnosed, an epidemiological investigation initiated, and information disseminated to thousands of practicing physicians. This rapid identification occurred even though the last case of inhalational anthrax in the United States occurred 23 years previously.

Eleven cases of inhalational anthrax eventually presented over wide expanses of space and time, and to physicians from multiple specialties; yet all cases were rapidly diagnosed and appropriately treated. Despite widespread post-event assessments of unexpected deaths, no additional cases of inhalational anthrax were found.

On May 13,2003, a three-year-old girl was bitten on her finger by a pet prairie dog. One week later she was seen by her primary care physician and was treated with antibiotics. Due to her worsening condition and a rash, she was hospitalized two days later. On May 25, a dermatologist was asked to see the girl. Biopsies showed characteristics of a viral infection. On May 27, her mother developed a similar rash and skin samples were taken for electron microscopy and other testing. On May 30, the illness was shown to be due to a pox virus and further testing was performed at the CDC. By June 12, CDC had released a fact sheet on this disease. This was the first known case of Monkeypox in the Western Hemisphere. It was diagnosed using the medical facilities found in a small town of 19,000 people in rural Wisconsin.

In the fall of2001 and in the summer of2003, something right happened and that something was found within the usual responses of dedicated medical personnel. This is the legacy of Abraham Flexner.

In both of these episodes, rare diseases, with which there was no previous experience, were identified by astute clinicians who did no more than what physicians are trained to do on a day-to-day basis. We start with undifferentiated symptoms and stories, use our training and experience to consider the possibilities, exclude some diagnoses through physical examination, the appropriate use of laboratory and other testing and, sometimes, the passage of time. We narrow the diagnosis. At each step, we depend on the context of our interactions and our knowledge of our patients and their families.

The members of the American Academy of Family Physicians see patients regardless of age, gender or affected organ system. We provide care in America's urban areas and rural areas. In many rural areas, we may be the only physicians that staff the emergency room, deliver babies and operate on patients. We provide a great deal of care to the indigent, the underserved and others left behind by our medical care system. Without family physicians, 1332 of this nation's 3082 counties—or 43 percent—would become Primary Care Health Personnel Shortage Areas, joining the 25 percent of counties that already are underserved.

Surveillance

Disease surveillance and detection ultimately depend on the patient-physician interaction. It is from this interaction that the core ingredients of surveillance emerge. They may take the form of individual patients matching a set of criteria, and those patients being reported to a public health agency—known as *sentinel surveillance.* They may be the one or two diagnostic codes that are assigned to describe the entire interaction for billing purposes—often used for *mechanistic or electronic syndromic surveillance.* They may be in the form of the diagnostic tests that are ordered at an encounter, forming the basis for *laboratory surveillance.*

Sentinel surveillance uses the human element to identify individuals in the population fitting a set of characteristics. It can be accurate and timely, but is limited by multiple demands placed on the sentinels. Nevertheless, approximately 1,600 family physicians currently participate in the U.S. Influenza Sentinel Provider Surveillance Network, a nationwide program for influenza surveillance run by the Influenza Branch of the CDC.

Mechanistic surveillance makes use of already collected data such as billing codes, pharmacy sales, hospital admission diagnoses, or other creative entities to rapidly identify changing patterns of disease or utilization. Data quality, the knowledge of underlying processes, and the reasonability of extrapolations limit mechanistic surveillance.

Laboratory surveillance provides the highest quality data, often using "gold standard" tests. It is limited by time delays, costs and lack of sensitivity.

All these forms of surveillance are useful and vital in an age of emerging microbial threats. The differing methods are complimentary. In the context of biological terrorism, however, they are all cursed with a fatal flaw. Biological terrorism de-

mands extreme timeliness and high sensitivity. When surveillance tools with these characteristics are applied to extremely rare conditions, as is inherent in biological terrorism, they will produce false alarms at extremely high rates.

False alarms are costly in terms of the subsequent epidemiological investigations, the potential to create fear and panic, and the tendency for habituation—that is, learning to ignore the alarms.

The greatest role played by physicians following the anthrax release of 2001 was not treating cases of anthrax, but, rather, dealing with the fear and panic of their patients. Allison McGeer—from one of the Toronto hospitals affected by SARS—recently noted that it was "easier to control the disease than fear." In the face of biological terrorism, the reassurance of a trusted doctor is invaluable.

What, then, is the most compelling role of surveillance in biodefense? I must reiterate that surveillance is essential and of utmost importance for homeland security. Surveillance must first have multiple use functions. For biological terrorism and other rare events of public health, the primary role of surveillance is to set the background against which unusual clinical events can be evaluated. A well-informed astute clinician is better than an astute clinician.

Family physicians are at the core of biodefense by nature of their widespread location, their permeation into rural and urban areas, the scope of practice-from outpatient setting, to emergency rooms to intensive care units-and by the volume of care offered to the American populace. On average, family physicians see 90.7 patients per week in outpatient settings and deal with an average of 3.05 problems per patient encounter. Given the number of active family physicians, one can estimate that family physicians may deal with well over one billion separate medical problems each year in the United States.

When this number of problems is coupled with the contextual nature of primary care relationships, and if background information can be provided to clinicians on community trends in disease occurrence through surveillance systems, the value of the astute clinician is greatly enhanced. This is the core of rare disease detection and of biodefense. In addition to the continued support of primary care physicians, three additional components are necessary for biodefense:

(1) an understanding of the role and function of the public health system.

There must be a core component of public health practice and epidemiology within medical school curriculum and residency training.

(2) connectivity of clinicians to sources of information on emerging threats that are rapid, redundant, reliable and relevant.

(3) easy and rapid means by which unusual cases and presentations can be reported to public health personnel.

The ability of clinicians to fill the role of the astute clinician is hampered by ever increasing demands of the medical care system. Primary care physicians have less and less time to fully evaluate patient concerns, faced with ever-increasing demands of workload and paperwork, regulations and managed care organization compliance.

We are facing a decline in the number of clinicians choosing to practice in the primary care fields. The number of positions for family practice residents peaked in 1998; the number of graduating family practice residents peaked in 2000. Because of the increasing costs associated with medical school training and due to decreasing reimbursement for the work that primary care physicians routinely do, an increasing number of medical students are choosing other nonprimary care medical specialties. National biodefense is dependent on a core of well-trained and widely dispersed primary care physicians.

The current medical system in America is strong and has shown its effectiveness in identifying and responding to rare emerging diseases. It is essential, however, to acknowledge the key role played in the defense against a new world of emerging pathogens by the thousands of primary care physicians that dedicate their efforts to the health and well-being of their patients and their communities.

I thank you for the opportunity to address the Subcommittee on Emergency Preparedness and Response and thank the Honorable John Shadegg for his invitation to provide this testimony.

Mr. SHADEGG. Thank you very much for your testimony.

Our final witness is Dr. Jeffrey Trent, president and scientific director of the Translational Genomics Research Institute. Dr. Trent?

STATEMENT OF MR. JEFFREY TRENT, PRESIDENT OF THE TRANSLATIONAL GENOMICS RESEARCH INSTITUTE AND FORMER DIRECTOR, NATIONAL HUMAN GENOME RESEARCH INSTITUTE

Mr. TRENT. Good afternoon, Mr. Chairman and members of the committee. Thank you for this opportunity to present.

My name is Dr. Jeffrey Trent and I am the president and scientific director of the Translational Genomics Research Institute in Phoenix. Prior to my move to Arizona 8 months ago, I served for nearly a decade as the scientific director of the Division of Intramural Research for the National Human Genome Research Institute at the National Institutes of Health in Bethesda. I am accompanied by Dr. Paul Keim of Northern Arizona University, one of the foremost experts in the forensic analysis of pathogens, and Dr. Paul Tracy of Stanford Research Institute.

I have been asked to speak briefly on the dangers posed by a biological outbreak and the need for comprehensive end-to-end solutions to these events. I would like to emphasize several points for your consideration.

First, if history repeats itself we will be presented at the time of a bio-threat crisis with sick and dying people or animals, and the answer will lie in how quickly we can detect and identify these early cases. During the training of physicians, you are often reminded that if you hear hoof beats behind you, look for a horse and not a zebra. But to some extent, this logic is reversed in bio-threat identification. That is, it is important to develop new approaches and diagnostic tests that might reliably separate a bio-threat from a new pathogen from the background of the common cold or flu which may cause similar symptoms. We believe that one possibility for this is reading the signature of the pathogen in the host as a critical feature.

Mr. Chairman, for nearly 20 years I have worked to create and utilize tools, many from the human genome project, to identify the genetic signature of killers. I have worked on killers such as breast cancer, leukemia and melanoma. I had the privilege at the National Institute of Health of also working to identify the genetic signatures or molecular fingerprints of killer viruses such as HIV, various T-cell leukemia viruses, and in collaboration with investigators at Fort Dietrich, being able to expose cells from individuals with the dreaded ebola virus at different virulence to look at those effects. We believe that molecular signatures of either naturally infecting viruses or bio-weaponized strains can be identified by surveying a response in the host.

So I can emphasize one critical element today, and that is that early detection is the key. The reason that early detection is the key is that it will mean faster diagnosis and faster diagnosis will save lives, optimize treatment selection, enable rapid triage of at-risk population, and as we have just heard, will provide the vital goal of reassuring the worried-well and reduce public panic. To achieve this goal, we believe there are three major elements that in a systems approach must be put in place: 1) the molecular signature that I have spoken of previously; 2) very low-cost diagnostic platforms that can work in a variety of clinical settings and including of course the comprehensive care physicians; 3) a national in-

formation architecture that allows incident progression and containment action to be monitored and provided to relevant key decisionmakers within the medical and public health community and decision support systems.

This powerful end-to-end solution is really an obligate demand for also including, as we have also heard today in testimony, public-private partnerships in the solution to this. It really requires that effort. In that regard, I have joined my colleagues Dr. George Poste and Paul Keim, as well as members from Amersham Biosciences and Stanford Research Institute in trying to develop one of the types of end-to-end solutions, something we call Project Zebra, as one of the solutions for such a complex problem, to allow faster mobilization of incident management as one piece in our early detection network.

In closing, I would like to thank you, Mr. Chairman, for convening this hearing on an extremely critical subject matter, and offering the opportunity to testify before your distinguished subcommittee.

Thank you.

[The statement of Mr. Trent follows:]

PREPARED STATEMENT OF DR. JEFFREY TRENT

Good morning, Mr. Chairman and Members of this subcommittee. My name is Dr. Jeffrey Trent, and I am the President and Scientific Director of the Translational Genomics Research Institute in Phoenix, Arizona. Prior to my move to Arizona 8 months ago, I served for nearly a decade as the Scientific Director of the Division of Intramural Research of the National Human Genome Research Institute of the National Institutes of Health in Bethesda, MD. I also wish to thank the members of the Subcommittee on Emergency Preparedness & Response of the House Select Committee on Homeland Security and Chairman, John Shadegg for inviting us to testify at this hearing today.

I have been invited here today to speak briefly on the dangers posed by a biological outbreak and the need for a comprehensive and effective end-to-end solution. I commend you for your willingness to hear from representatives of the medical and scientific community about this serious and important issue. Both my colleague Paul Keim, and I represent many who are ready to work toward addressing shortcomings of our early detection and treatment capabilities.

Mr. Chairman, I would like to emphasize several points for your consideration.

First, history tells us that pre-exposure detection is not feasible—we will be presented at the time of a bio-threat crisis with sick and dying people or animals, and the answer will lie in how quickly we can detect and identify these early cases.

Also, the answer will lie in new approaches to diagnostic tests that can reliably separate bio-threats of new pathogens (such as SARS) from the background of the common cold/flu which may cause similar symptoms—thus ″reading the signature″ of the pathogen in the host is critical. Joshua Lederberg,[1] a Nobel Laureate once said: "The single biggest threat to man's continued dominance on the planet is the virus." With the September 11 terrorist attack and subsequent anthrax attacks, what was once a topic popularized for science fiction is now a startling reality for all of us.

Mr. Chairman for nearly 20 years I have worked to create and utilize tools and techniques to identify the genetic signature of killers. I have worked on killers such as breast cancer, leukemia and malignant melanoma. While at the NIH I also worked on identifying the genetic signatures—the molecular fingerprint—of killer viruses such as HIV, human T-lymphotropic virus type 1 (HTLV-1), human herpesvirus 8 (kaposi's sarcoma-associated herpesvirus), and in collaboration with

[1] Dr. Lederberg is known for his studies of the genetic mechanisms of bacteria. He shared with G.W. Beadle and E.L. Tatum the 1958 Nobel Prize in Physiology or Medicine for establishing that sexual recombination occurs in bacteria. Lederberg showed that although bacteria reproduce only by dividing, they are able to affect sexual recombination by processes that result in exchange of genetic material between different bacteria. In 1978, he joined Rockefeller Univ.; where he served as president until 1990.

investigators at Ft. Dietrich, the dreaded Ebola virus. We know now that a molecular signature of a naturally infecting virus, or a bioweaponized strain of anthrax—can be identified by surveying the response in the host.

But, while there is hope that we may be able to identify by diagnostic testing a biothreat's genetic signature—the most important thing I can emphasize today is that an end-to-end solution is critical, and that early detection is the key. Mr. Chairman and Committee Members, the reason that early detection is the key is that it will mean faster diagnosis—and faster diagnosis will:

- Save lives
- Optimize treatment selection, and
- Enable the rapid triage of at risk populations

(which will provide the vital goal of reassurance to the worried well (thereby reducing the risk of public panic).

To achieve this goal of early detection four elements must be in place: and as this is a systems-based approach to the problem, the failure to develop anyone of the four will not address the critical needs in biodefense and improved public health and safety.

- **Molecular Signatures (BIOPRINT):** Gene and protein sequencing of selected pathogens; detection of genomic, proteomic, and phenotypicsignatures of the host immune response, and the creation of unique marks for a broad range of biothreat.
- **Diagnostic Platform (ZPD):** Incorporating the signatures into a low-cost diagnostic platform suitable for routine patient testing in a variety of clinical settings.
- **National Information Architecture (Bioincident Warning and Communications System—BWACS).** Integrated collection of data, syndromic surveillance, reliable anomaly detection, and real-time alerting of local and national decision-makers that a bioincident has occurred and permit real-time assessment of incident progression and the effectiveness of containment actions. And,
- **Decision Support Systems**—An infrastructure linking key decision-makers with relevant medical and public health authorities to ensure rapid launch of optimum treatment protocols, rational allocation of drugs and vaccines, and comprehensive incident containment actions.

Mr. Chairman and Members of the Subcommittee, currently, health providers do not have the necessary tools to distinguish between an infection caused by a bio attack and .that caused by the average cold. They must rely on a series of sequential, inefficient and cumbersome actions that delay mobilization of prompt responses.

The requirement I believe is the pursuit of a purposeful end-to-end solution of all four of the aforementioned system elements—something that will require an obligate demand for public/private partnerships.

This is what has driven me to join my colleagues, Dr. George Poste and Dr. Paul Keirn, in a consortium involving the three universities in Arizona, linked with Dr. Michael Tracy and his team at the Stanford Research Institute, International in Menlo Park, California, with the involvement of one of the leading manufacturers of chip-based technologies, Amersham Biosciences, in New Jersey, in the development of a project called the Project Zebra, which can be part of the solution for this complex problem, allowing faster mobilization of all relevant incident management actions, a key piece in early detection.

In closing, I would like to thank you, Mr. Chairman, for convening this hearing on an extremely critical subject matter and offering me the opportunity to testify before your distinguished subcommittee.

Mr. SHADEGG. Thank you, Doctor.

I appreciate the testimony of all of our witnesses.

Before we begin our questioning, Dr. Trent I understand that you would like to have Dr. Paul Keim, who is an expert in anthrax and plague, join you and complement you in answering any questions. Is that correct?

Mr. TRENT. Yes, sir.

Mr. SHADEGG. Dr. Keim, welcome. Would you state and spell your name for the record please?

Mr. KEIM. My name is Paul Keim. The last name is spelled

K–E–I–M. I am the Cowden Endowed Chair in Microbiology at Northern Arizona University and the director of pathogen genomics at T–Gen.

Mr. SHADEGG. Thank you and welcome.

Let me begin the questioning. Mr. Henderson, let me begin with you. You made a reference to BioWatch in your testimony. BioWatch intrigues me. It is something I believe could go a long ways toward protecting the American public. I would like you to tell me about your work with the Department of Homeland Security on the BioWatch Program, and how the investment in disease surveillance fits into that equation.

Mr. HENDERSON. The BioWatch Program is a program that is a collaboration. It is being led by the Department of Homeland Security and CDC and the Department of Health and Human Services are supporting the concept of BioWatch. Fundamentally, what it is and how it works is there are a number of air samplers placed in participating cities. This is right now a proof of concept. We want to make sure it works and contributes to the overall detection system in a particular community.

Staff from the public health laboratories will on a routine basis collect the filters in these air samples that are placed in strategic locations, subways et cetera, and they will run tests across those filters to see if they detect any type of pathogen. If they do in fact detect a pathogen, then there are consequence management plans in place to execute or mobilize a response to determine who may have been exposed, if there is still agent in the atmosphere, et cetera.

Again, this is a proof-of-concept phase. It is taking place in a number of cities. We are trying to build systems to assure that once we have true positives, we can mobilize a response rapidly, but also develop a system for false positives which we feel could be a potential problem in the future.

Mr. SHADEGG. I understand this is an airborne detection system.

Mr. HENDERSON. Right.

Mr. SHADEGG. Is there thought being given to other types of detection systems, for example, in a water system?

Mr. HENDERSON. We have had discussions, but we have not yet developed a program to begin monitoring water.

Mr. SHADEGG. Okay.

Dr. Trent, Project Zebra. It seems to me this holds tremendous potential. I would be interested in how genomics links into Project Zebra and how realistic it is. Maybe you should describe Project Zebra in a little greater detail and how realistic the concept is in terms of creating a device which could be used even in an individual doctor's office to detect bioterror attack.

Mr. TRENT. Sir, clearly as one piece of the puzzle, we just heard environmental sensors are important, but we do think that biomedical sensors are equally important. The focus on people is as important as the focus on the environment. What we strongly believe is as you have heard for the distribution system of information within the health sector, that many of the available components that we have today for recognizing the signatures of pathogens and the type of hardware and software that is needed for a comprehensive program is in fact in place and capable. I think that

my colleagues, Dr. Keim might have also have a comment in regard to that, with your permission.

Mr. SHADEGG. Certainly.

Mr. KEIM. So how I can address that question best is based upon our experience in the anthrax letter attacks. It may sound crazy, but in fact we were better prepared for an anthrax attack than any other pathogen, which is scary to think about. We had very highly developed genomic analysis already in place. In fact, we had analyzed the type of anthrax and knew probably where it came from before the first victim died in Florida. That type of very early-on information is really a type of genomic signature which gives you the information that in fact this was a bioterrorist attack.

There were in fact many naysayers in those first few days that did not think that this was a bioterrorism attack, but the identity of the strain and its probable source from a U.S. laboratory put all that to rest. So Project Zebra is in fact an information enhancement upon the current type of diagnostics that we have. The more information we can get and the earlier-on that we can get it about any type of disease, but in particular in this case bio-threat pathogens, is just going to lead us to better treatment and better response modalities.

Mr. SHADEGG. You indicate that we already had the signature on hand for anthrax. Are we developing those signatures for all of the other pathogens that might present?

Mr. KEIM. Absolutely, Chairman. We have been funded by the Department of Homeland Security and its predecessors for nearly a decade to do that. We are developing these signatures to work in the framework of BioWatch so that we can get the information such as I described from the very first moments of the detection process.

Mr. SHADEGG. Dr. Temte, there was an article which appeared in the September–October issue of Health Affairs which surveyed a number of physicians across America and found that only 20 percent of physicians felt well-prepared to play a role in handling a bioterrorist event. My first question is, do you think that is an accurate result? Second, why is that the situation and what can be done about it?

Dr. TEMTE. Very good questions, Mr. Chairman. I would agree that that is probably a good estimate of the current state of affairs. We ran a focus group of family physicians prior to the anthrax events in March 2001. At that point in time, people said we would not recognize any of the classic signs or symptoms of anthrax and we are not prepared. We had the opportunity to repeat that in March 2002. The big change was that everybody said yes, we know the basic diagnostic pattern of anthrax. We will recognize the chest x-rays and so on. We are still not prepared. We do not know what to do with preparedness planning.

So I think in the big picture, physicians in general have very little training, very little information on what to do if there are mass casualties, if there is mass panic. Whereas hospitals are required for accreditation to have emergency preparedness drills, most physicians do not participate. Most physicians are not hospital-based, but are clinic-based, and there is no incentive. To be honest with

you, for most physicians there is no time to take out of a very packed schedule and participate in a half-day training exercise.

Mr. SHADEGG. Thank you very much.

Mr. Thompson for questions?

Mr. THOMPSON. Thank you very much, Mr. Chairman.

Let me compliment the panelists on your presentations. Dr. Keim?

Mr. KEIM. Yes, sir.

Mr. THOMPSON. For someone who might not be as up on pathogens as you would think, how many have we identified?

Mr. KEIM. How many different types of anthrax?

Mr. THOMPSON. Yes.

Mr. KEIM. In my laboratory, that is in fact exactly what we do. We have developed highly precise genomic analysis for identifying anthrax. We currently have a database that has about 450 unique types of bacillus anthracis or anthrax. That is based upon the world's largest collection of strains that exist anywhere in the world, right there in Arizona. So we have about 450. So in those early hours, we were able to zero in and say this strain that came from the victim in Florida belongs to this particular category, and that category has only been found in nature once. I can tell you exactly where in Texas that strain came from. I can tell you what cow it died from, and I can tell you its pathway up until it got to the U.S. Army. After that, I cannot tell you.

Mr. THOMPSON. Thank you.

Mr. Temte, what do you think we need to do to get physicians brought up to the level that you would feel comfortable in having them identify some of the problems we are talking about?

Dr. TEMTE. In a roundabout way, a concern I have is the direction that American medical practice took in diverging from public health practice approximately 100 years ago. These two practices, where as they have a lot of the same purpose and a lot of the same goals, operate fairly parallel. The amount of interaction has been far too little, especially I think we have seen that in the last decade or so.

That being said, in standard medical training quite often any approach to understanding epidemics, understanding the role of community, understanding some of these trends that occur beyond the level of the individual receive fairly short shrift. I think what is necessary is for us to incorporate into not only medical school training, but into residency training and into practice the means by which we better interact with public health.

Once someone gets into practice, one of the things that you find is quite often it is very difficult to establish any communication with public health. There was a mention of physicians being poor about turning in forms for reportable illnesses. I think if you polled most doctors out there, we would not know which ones were reportable or not. Why is that? Time and priorities. It is very difficult to sort out priorities in a busy practice. I have an HMO telling me all the guidelines I am not addressing with these certain patients. I have my HIPPA compliance. I have to think is this a disclosure or not. I have billing things. I have the ICD–9 codes which I have to pick from a list so someone knows that diagnosis I am making. All these things compete. So when it comes down to trying to commu-

nicate with public health and find that the person is not at the other end of the line, I get an answering machine or someone that is not there, it gets to be very, very difficult.

I think systems by which we can improve communication, and this has to be a two-way flow of information coming from clinicians to public health, to inform public health what is going on, but also the flow back to clinicians on a day-to-day basis about what is happening out there in the community. Are we in the middle of a flu outbreak? If that is, that really helps me address the concerns and the problems my patients are dealing with.

So we have to build better communication and be cognizant that communication systems need to be very succinct, very clinically relevant for clinicians. They have to be redundant and very reliable.

Mr. THOMPSON. Thank you.

One other question, Mr. Chairman. Dr. Platt, taking what you just heard and applying it to your operation, have you been able to streamline that? Have you been able to get the reporting faster? I would also like to know if you do, to what extent or what percentage of the country is using electronic medical records these days, or whether we are still doing it by hand?

Dr. PLATT. Really, you have put your finger on both the problems and the solutions, I think. In the systems where we are working, many of the problems that Dr. Temte mentioned are somewhat ameliorated. Stepping back a bit, I believe that our nation has been building a very powerful adjunct to the traditional public health system in the form of health plans. They know all the people for whom they are responsible for care. They have communications systems with the clinicians who are taking care of their patients. Their communications are bi-directional, though they are not as robust as they can and should be. And an increasing number are using various electronic methods to communicate information about their patients.

The direct answer to your question about electronic medical records on which we have built our system is that they are used in a minority of practices now. It is hard to predict how soon they will disseminate very broadly. On the other hand for surveillance in communities, it is not necessary for the whole community to be served by clinicians who are using electronic medical records. Coverage of 10 percent of 30 percent would probably serve very well to act as an alerting system. The communications part-back from the public health system to the clinicians, and through them to their patients-can be substantially enhanced by the health plan's existing communications mechanisms.

Mr. THOMPSON. Thank you.

Mr. SHADEGG. Ms. Dunn to question.

Ms. DUNN. Thank you very much, Mr. Chairman.

A fascinating presentation, panel, thank you for being here and giving us your time, because you are very helpful to us as we try to put some things together.

I am interested, and I am not quite sure whom to ask this question of, but I would like the broad-brush approach. Dr. Platt has some excellent pieces of paper that show us where there was a collection of outbreak of SARS, I think it was that you were showing us. Was that what that was?

Dr. PLATT. It was respiratory illness. There was no SARS in Massachusetts that I am aware of.

Ms. DUNN. My interest is directly related to communications with the Department of Homeland Security. So if you come up with this sort of an indicator that there is an amazing collection of illness in a particular part of our country, how long does it take you to decide whether it is a terrorist invasion, a biochemical or a chemical weapon of mass destruction? How do you get that information to the Department of Homeland Security? Do you have to wait until you know it is a terrorist-caused outbreak? How do you determine that? What is the process you go through, and perhaps Mr. Henderson needs to be involved in this too, in reporting that? Let me just add to the complications. What happens if we have this occurring on a night like last Thursday night when communications were knocked out all over the country? What is the process and are we sure we are prepared now to be able to get this information where it needs to be?

Dr. PLATT. I will begin and then defer to Mr. Henderson. The system that we have built is a real-time system. That is, it is possible to know very soon after the clinical encounter that there is a cluster. That is a considerable achievement. Interpreting that cluster really lies within the domain of the public health system. That is the point where I hand off.

Mr. HENDERSON. Nice segue. There are a couple of pieces to this. In my testimony, I talked about the creation of a bio-intelligence center, because we do need to have this data that is collected locally, analyzed locally first, and then of course captured on a national level and analyzed rapidly and then disseminated back to all the stakeholders who have a stake in making a decision to determine whether or not to fully investigate what they would perceive to be a potential blip on our radar that might indicate we have either a terrorist event or we are starting to see a potential emerging infection disease in our population.

So what we are looking to put in place as far as overall infrastructure I think amplifies our abilities to do that. I think today if you were to see clusters of disease, for example, generally young healthy people showing up in emergency departments, we are absolutely positively dependent upon those clinicians to call, be suspicious, and then depend upon the local and State health agencies to contact CDC so we can all support whatever response may be needed to investigate that and determine the extent of the potential issue in that community.

The question you raised about how soon would Homeland Security know, the minute that we find out from CDC, our emergency operations center communicates with the Secretary's command center in Washington. They are our vital link to the Department of Homeland Security. We essentially follow the command and control procedures that you see with the national incident management system. So there is that day-to-day ongoing connectivity, even when we see cases of disease say a full-blown illness outbreak, which we have been supporting at the State and local and Federal level for years. We include that information in our daily situation reports that go to Homeland Security, so they always have a sense of our background level of activity so that if they start to see an increase

in that activity, they can work with us to determine if we need additional resources to contain and control the event.

Ms. DUNN. That is very helpful. How does that connect to the Department of HHS, the stockpile, for example, of antidotes? Does that come from the Department of Homeland Security, the request to enter?

Mr. HENDERSON. Keep in mind the operational responsibility for the strategic national stockpile is at CDC. We work very closely with Homeland Security on managing the stockpile. We have done this through exercises and we actually did this in a few real circumstances. The request comes to CDC. We process the request and get approvals from both the Secretary of Health and Human Services and Homeland Security at the same time. When we have done this through exercises, it is done literally in a matter of just 1 or 2 hours.

Ms. DUNN. What happens if all communications are out? What do you do then?

Mr. HENDERSON. We have redundant communications capabilities.

Ms. DUNN. Good.

Mr. HENDERSON. That is very similar to the Secretary's command center in Homeland Security and the National Command Center in the Pentagon. We follow a pattern to have that redundant communication capability. The one issue you brought up that we realized during the blackout of a few weeks ago is that our health alerting technologies are all dependent upon electronic transmission of an e-mail, essentially. So we were putting out health alert notices to talk about your water systems, what to do with food that would spoil in your refrigerator. Obviously, it is getting to all the people who have electricity and not getting to those who don't.

Ms. DUNN. The ones that have the problem.

Mr. HENDERSON. Right. One of the lessons that we learned from a visit to Israel was they have a standing public radio station that is always there that people know to tune to, and we have had discussions at Homeland Security about standing up that radio station so that people would know in a power outage when they pull out their family preparedness kits which include a radio and batteries, they would know this particular channel to tune to to get information in the absence of power.

Ms. DUNN. Good. Thank you very much.

Thank you, Mr. Chairman.

Mr. SHADEGG. Mr. Turner to question.

Mr. TURNER. Thank you, Mr. Chairman.

I want to direct my question to Dr. Trent and Dr. Keim. You have heard, and I am sure you are very familiar with, the pilot projects that place environmental sensors in different locations in our country to collect air samples, which are then collected and analyzed.. We could spend a lot of money doing that. What I would like to know from you, and have your expert opinion on, is whether it is better to proceed with investing millions of dollars in environmental sensors, or should we-and specifically can we-develop a biomedical center that could be used for immediate detection of infectious diseases, whether it is an engineered pathogen or a naturally

occurring one; I'm referencing a device that could provide a diagnose within minutes after a blood sample was taken. Then whether we could develop the capability to analyze that information and be able to develop a response to it in a short period of time?

I know I am asking for the moon and the sky here, and I know we all understand that our traditional patterns of developing vaccines takes years, but if I was asking today for what I think is the answer to dealing with the terrorist threat that I know we are going to face just as soon as they gain that capability, it seems to me that we have got to have an ability to detect these threats once symptoms manifest themselves and the ability to then rapidly develop a response, a treatment, or an antibody.

I also would be interested not only in your advice as to whether we have the capability to do that, but whether that approach could also be helpful in dealing with ordinary illnesses, so that we might not pass out quite as many antibiotics in this country when, as all of us know, antibiotics are over prescribed and over used. Could we find some dual use in that kind of capability that would allow us as a government save money in other areas of healthcare, simply because we have been willing to make this kind of commitment to protect Americans against terrorism? but also to protect us in other public health areas.

I know this is a big wish list, but I just want to know if, from your vantage point, it is feasible, what would the costs be, and whether there are some offset savings.

Mr. KEIM. That is a great question. I don't know where to start on that, except to say that we will always in this country need to have some type of environmental monitoring. The Super Bowl is a good example, or the Olympics. There are places where we are going to have environmental monitoring. But we are not going to be able to protect this entire country through environmental monitoring. The task is just incredible. The spatial scale and the breadth of pathogens that we are talking about that can be used in bio-crimes or bioterrorism events are just too enormous.

However, if you focus upon the point, which is the patient and the individual, and we start to use our genomic information and knowledge about human response to pathogens, I think that there is a real key here for where we can start to unify this monitoring. Again, it starts with the clinicians at the public health sectors, and then accumulating that information. A good example of what you talk about are in fact these strep tests that pediatricians use every day to try to decide if you give a kid antibiotics, if you say it is a virus or if it is a bacterial. So that is a very rapid, high-value of information that comes back to physicians, allowing them to make clinical decisions and therapy decisions right then and there. I think that this is not going to be available in 6 months, but I think it will be available in 2 to 5 years. I think that is the scale, and we have to invest today if we are going to get there in 2 to 5 years.

Mr. TURNER. You are talking about a detection device that could be made available to a local hospital or a local doctor's office?

Mr. KEIM. That is right. Your point is also very good about branching out. If we are focusing upon the patient, we are going to be moving beyond just whether it is anthrax or plague or small-

pox, which is really a very low return on your day-to-day operations. But in fact if you are starting to get back more information to physicians, it is just going to move over into all of these different pathogens that they are going to be using on a daily basis. That is the only type of system that is going to be sustainable in the long term. If you going to focus for the next smallpox attack, we are going to lose interest in this country very quickly. Yet if you are monitoring and physicians are getting feedback on these diseases on a daily or even an hourly basis, they are going to use them and they are going to use them on a regular basis. Then we will be ready for when hopefully that one bioterrorism event occurs next.

Mr. TURNER. So you can develop the device to know what you are dealing with.

Mr. KEIM. Absolutely.

Mr. TURNER. That is within the realm of possibility?

Mr. KEIM. Absolutely.

Mr. TURNER. Can you answer the question I asked about once a diagnosis is made whether we can develop a capability to develop some response to it in a shorter period of time than we normally have available today?

Mr. KEIM. I think we have some great examples of where that is already occurring. The response to HIV may have taken us a decade, but we could not have done that 10 or 15 years ago. The therapeutics that are available now for HIV–AIDS patients are an amazing success story of our development of drugs in response to infectious diseases. You are probably asking can we do it in minutes. Well, if we have to respond in minutes, physicians are going to have to go for what they have on the shelf now, and in many cases that will be adequate. Antibiotics, there are new antivirals cropping up. Even without knowing exactly what that pathogen is, there have to be strategies that would be preferred or more probable of having success, given our knowledge of what is going on and how the patient is responding to this event.

Mr. TURNER. Who is responsible for detection the private sector or the government? What entity is going to be responsible for responding to the unknown?

Mr. KEIM. Traditionally it has always been a partnership between the private sector and government. Government usually has to invest money into the high-risk aspects, and then the private sector can pick up and run with the more commercially viable commodities such as the drugs that can make money. Those drugs would not be possible if the government does not sink that investment money in it, and maybe years ahead of time. So that is a very important component of the success in our biomedical area.

Mr. TURNER. Thank you. My time has expired.

Mr. SHADEGG. Dr. Christensen to question.

Ms. CHRISTENSEN. Thank you, Mr. Chairman.

I would like to just make a few comments for the record. I want to thank you for this hearing. It is getting closer to some of those critical issues that we have been advocating for since this committee was established. While I am happy that we have begun to look at some of the more basic and important issues, I am still concerned that we are perhaps missing the mark because we are not,

at least at the same time, focusing on the infrastructure needed to mount the response. I see my fellow family physician nodding in assent, as I was during your testimony.

If we know what we have and we are not able to respond because the facilities are not prepared, labs are not up to date, staff are not properly trained, we will not save lives. I think when we even look at the SARS epidemic, it is plain old ordinary public health and I am sure a lot of family physicians and other primary care providers saved the day. So I still hope that we will take a look at where our public health infrastructure is, because that is really critical.

I know that in a demonstration program, Dr. Platt, if I read it properly, it deals with people just in the plans. It is a demonstration program, so it is really people in plans. As an African American and knowing that people of color are over 50 percent of the uninsured, and that our communities have the worst public health infrastructure, I am concerned and I am wondering how would we propose to do surveillance in populations that wait until the last minute to get care because they just avoid it, and those where there are not culturally competent physicians, they may be understood, so diseases may not be picked up. How do you propose to do that? If I was a terrorist, I would go to the weakest place, right there.

Dr. PLATT. You are touching on an enormously important and difficult problem. Our horizon really is the medical care system such as it is. The couple of things worth noting are that all of the plans that we deal with have quite diverse populations. On the other hand, they are all people who have some kind of insurance. But we are also in discussion with local health departments that are the providers of care of last resort in many communities, and are far along in discussions about having them behave like health plans with respect to the system.

So it is our expectation that in the very near future we will have a new major contributor of data that is a local health department that is responsible for the care of the indigent population. It is a little different from the usual defined populations that we deal with. On the other hand, it is a recognizable population, too. So it is our expectation that to the extent that this mechanism proves to be useful, it can also be a useful aggregator of information that comes from those provider systems that deal with the traditionally uninsured populations.

Ms. CHRISTENSEN. I recognize that you stress the importance of the public health, the private sector and academia working together. This is a concern that I always have and I think we all should have.

Dr. Temte, I quoted you in our press conference today. It is always good to have a fellow family physician on the Hill. I think Representative Thompson probably asked my question around the communication between the CDC, for example, and the private physicians. If you wanted to add to you answer, I would appreciate it. But I was also wondering how much and how accessible have you found training to be for physicians in bioterrorism, and who has offered it, and have many physicians in your community taken advantage of it?

Dr. TEMTE. I will answer your question, and I am going to pick up a former point before that, and that is the whole area of access to care, which I think is so very important not only in urban clinics, in urban settings, but also rural areas. I practice in a medically underserved area in an urban center in Madison, Wisconsin, in a very diverse patient population. The patients that I see that have disease that is far advanced, for example, a diabetic coming in with a toe that is gangrene, are my patients who have no insurance; who feel disconnected from the community.

I absolutely agree with your statement that if I were a smart bioterrorist, I would target an inner-city uninsured group of people with a lot of illegal aliens. I would target them with something that is contagious and it would brew there and it would seed, and they would take it into emergency rooms where they will sit for 10, 12, 14 hours and infect people there. And a number of them, like a number of our patients once they get sick, would head to Mexico because they can get care there. So I really pick up on that point on access to care. We have systems that will pick up things if someone is insured, but we don't pick them up very well if they are not insured.

Another point was made about systems by which we can get lab tests on all patients with respiratory illness, for example. There are close to 800 million ambulatory care visits in this country each year; 11 percent of those visits are for acute respiratory infections. When you look at any laboratory test, and especially if you have one that will give you the answer on 300 different pathogens, I can assure you that a number of those are going to be automatically falsely positive. If I am a clinician and I do a test on a patient and it shows positive for anthrax, what happens if I go to my local news media and say, hey, I have a patient here with anthrax; or hey, I have somebody with smallpox. This is a reality of any lab test. There are false positives and false negatives, and there will always be false positives and negatives.

So you have to be very, very careful when you apply a test to a broad population that is less than perfect and you are looking for something incredibly rare. Responding to false positives is incredibly expensive. We need to get some information from our public health sector about how much it costs to chase down false positives when they emerge.

I really got off the track there.

Ms. CHRISTENSEN. I am glad that you took the time to give that response as well. Go ahead.

Dr. TEMTE. I got so far off the track that I forgot the question. My apologies.

Ms. CHRISTENSEN. I was just wondering, as a practicing family physician, how accessible is training for physicians in bioterrorism?

Dr. TEMTE. An excellent question. To best define that, I think you have to look at what type of training is appropriate. There was a consultation at CDC in January 2002 looking at how do we train clinicians for bioterrorism and other emerging threats in the public health sector. There is a real differentiation between just-in-case training and just-in-time training. Just-in-case means going out and training clinicians to be very aware of the symptoms of tularemia for example. I have given talks on tularemia and I would

have to go back to my notes to look up what the symptoms are, because it is just not important to me.

Just-in-time training, however, is when there is a threat out there, then we can get information that is factual, that is reliable, and that is very succinct and takes no more than a minute for a busy clinician to look at. If we can get information like that, and I will give a big nod to CDC, their information on the Web pages for clinicians is wonderful. I used that a lot for SARS. Because Wisconsin was the epicenter of monkeypox, I used the information there and was up very quickly. The information for clinicians on monkeypox was posted on June 12. This is just within days of the diagnosis being made. So the communication aspects to clinicians are very important.

Let me give you one other example. I gave a grand rounds in bioterrorism to my hospital in June 2000. I had a handful of clinicians come. Their response was, this is interesting, but not very relevant. In November 2001, I gave basically the same talk to the best-attended-ever grand rounds at our hospital, where not only were there family doctors and cardiac surgeons and neurosurgeons, but the anesthesiologist and the support nurses and everybody else was there.

There has to be systems to get information out very quickly, train out very quickly, but I do not think it is going to work very well to get training on multiple pathogens that are irrelevant to everyday practice done in a advance.

Mr. SHADEGG. The time of the gentlelady has expired.

Mr. Shays to question?

Mr. SHAYS. Thank you, Mr. Chairman. Mr. Chairman, thank you for holding what is a very, very important hearing. I appreciate our panelists who are all, I am sure, giving this a heck of a lot of thought.

In my Subcommittee on National Security, we had a doctor with a major medical magazine 4 years ago before September 11 express at the end of the hearing his major fear, and his major fear was that a small group of dedicated scientists could create an altered biological agent that could wipe out humanity as we know it. I am learning that that may be a fear that is unlikely, but still possible.

When I was meeting with the World Health Organization in Geneva, they told me SARS is going to be back, and that there are 30 other new pathogens out there and who knows what. So I am struck by the fact that whether it is man-induced or natural causes, this has tremendous benefit for society and we probably should have done it a long time ago, even if there wasn't the threat of terrorism.

What I would like to know is a few things. I would like to know how we fuse the non-patient specific data with the patient-specific data, like pharmaceutical sales and health plan nurse call-in topics and so on. How does that all get integrated? I do not know who I should be asking.

Mr. HENDERSON. Probably I should be the first to touch on this, and then Richard you may want to add something to it.

Right now, it does not happen. It happens in some localities, for example New York City where they have looked at data post–9–11 and they are trying to find ways to assimilate that data and have

it influence their decisionmaking. In my testimony, I talked about the creation of the bio-intelligence center which is a conceptual process at CDC where we are looking to take these streams of data, have algorithms developed that will allow us to look for any suspicious clusters of disease presence in the population, and then provide information back rapidly to States and local public health agencies. We have not completely developed that yet, but we are moving fast and furious to do that.

Mr. SHAYS. Will we have to pay people to provide this information every day? Or will we just require it by law?

Mr. HENDERSON. That is a good question. I think the data that we are talking about, at least as it supports this notion of bioscience, is already existing streams of data that I believe we are going to depend upon to help give us some information. As we build our bio-intelligence center and we see that there is other valuable data components that we would like to feed into that, we may have to buy it. We may have to ask for legislation, if in fact we find the data to be that valuable.

Mr. SHAYS. I would think right now, though, that you would find a lot of folks out there who want to cooperate. Is that a fair statement?

Mr. HENDERSON. Yes.

Mr. SHAYS. Okay. Who could speak to the technology that is involved in this effort?

Mr. HENDERSON. I could refer to Dr. John Loonsk, who is with me. He is our director of informatics at CDC. Perhaps John could add a few comments.

Mr. LOONSK. Thank you. I am John Loonsk. To partly address your question about costs, there are a great number of people who are interested in providing data for these purposes, but there are still costs to get data out, to integrate the systems to make them work together. That is one of the costs that we face.

Technology is also an issue involved with what Dr. Platt spoke about earlier, which is that electronic medical records do not exist consistently nationally, and where they do exist they do not always store the same data. When you are collecting that data to use them together, that becomes an issue, so that you want to compare similar data and use them in a similar way. But there are a number of other data sources that are viable, such as clinical testing that is done; there is interest in over-the-counter drug sales and how they may be predictive for populations that are not represented in traditional health care as well.

Mr. SHAYS. And will we be collecting this information state by state, or are we looking to do it nationally? What is the model going to be?

Mr. LOONSK. Some of the data sources are very specific and very local, an individual hospital.

Mr. SHAYS. I know it is local, but is it going to be sent to a State repository or is it going to be sent to a national?

Mr. LOONSK. The proposal in BioSense is to share the data at national, State and local levels, to be able to provide the data to the jurisdiction that is analyzing those data.

Mr. SHAYS. I am a little confused by that. The model we are using right now is it is going State and the State is then sharing

it with the Federal Government? Is that basically what we anticipate happening or are we going to bypass the States and just send it right nationally? Or do we know?

Mr. LOONSK. We anticipate both these paths actually to exist for some time. The traditional path of clinical, local, State, Federal and we think we can leverage data sources that may be accumulated at the national or regional level and use a single connection to that data source to then provide it to the State level or to the local level.

Mr. SHAYS. Thank you.

Thank you, Mr. Chairman.

Mr. SHADEGG. I thank the gentleman for his questions.

I am just going to advise the members of the panel that I am at least going to ask one question in a second round, and I have let Mr. Turner know that he may do so if he would like to.

I want to follow up quite frankly on Mr. Turner's questioning. He asked some questions about the issue of environmental sensing, and I understood Dr. Keim to say that environmental testing was going to be a part of what we needed to do, and certainly there would be areas where you could do environmental testing. You mentioned sports arenas or something of that nature. But that environmental testing of the entire nation may be looking too far for that prospect.

I want to focus on the other type of testing, which is what I understand Project Zebra to do, which is testing which occurs on a patient-specific basis. There was some discussion here which has confused me on false positives. When you do a lab test, you can get a false positive. Everybody understands that. What I am trying to get a clear understanding of is that as I understand Project Zebra, it is the development of the analytic information and the loading of information into a testing device that could be inexpensively purchased and created, inexpensively enough so that as I understand it it could go in an average practitioners office or in an emergency room where there were uninsured patients or illegal aliens or others in the country who were not insured. And that through using genomics, it can test for at least these bioterror pathogens that we are interested in and give you a result back, and give that result back, as I understand it, instantaneously. My question is, is that correct, that understanding of the way Project Zebra is working? And how realistic is it?

Finally, using genomics to perform those tests, do we eliminate the possibility of false positives or false negatives? Or do we diminish it dramatically? Where do we stand with that?

Mr. TRENT. Starting with the last question, you absolutely will never eliminate entirely false positives or false negatives from any test. Anyone who testifies to the contrary would not gain credibility with anyone, I am sure, including this committee. Certainly we recognize that. But there are clearly going to be occasions, including for example the unforeseen but difficult situation of thousands of individuals presenting for triage within an emergency response center that rapid identification may be an important component of the triage process.

The power of genomic technology will allow us to identify fingerprints for many pathogens. It won't eliminate completely by any stretch of the imagination false positives. But if we are looking for

a Zebra of course to other common physiological responses in the context of a smart physician looking more broadly than just a single test. They don't do that now. They look at a test, incorporate it with the rest of their information, and then make a judgment. I think that we want to be believe that these type of approaches will add value to the practice setting in the combination through an educated physician.

Mr. SHADEGG. Is it practical to develop a machine at that expense level?

Mr. TRENT. I think so, absolutely. I think the goal for this type of a project and others like it are to have the testing cost driven down to a level to where it can occur within a population base, and that the actual detector instruments have to also be driven down in the cost estimates to be able to be placed within the framework of physicians's offices. So the answer is absolutely.

Mr. SHADEGG. Thank you very much.

Mr. Turner?

Mr. TURNER. Mr. Henderson, you mentioned that we are doing some experimental work with those environmental sensors, called BioWatch and we are funding that research, I assume. Are we doing any research into these biomedical centers that Dr. Trent is referencing?

Mr. HENDERSON. We are clearly supporting the research that is being done. At CDC we have looked at a whole variety of hand-held devices to determine whether or not it would actually prove valuable. I have to say we have dedicated a lot of time and effort in responding to events that were triggered by some of the hand-held devices, not these particular devices, that were all not true events, and created a lot of problems, frankly, in our response systems.

The one thing I just wanted to mention because it seems to me there is a theme forming around the use of these early detection systems. When looking at detecting a pathogen in the population, it is critically important that we have the tools necessary to confirm a particular organism as soon as possible for those first few cases. You will not continue to look to detect and confirm in every single instance once you see you have certain diseases in the population. This is where we become more dependent upon case definitions, because then the focus has to be on your response and how can you rapidly bring about the countermeasures so that you can halt disease transmission and reduce the severity of the illness and hopefully prevent additional deaths.

I just bring that to the committee's attention because it is important to know that. We would not look for hand-held devices per se for every case where a person has certain symptoms to confirm that this particular person is sick because of this causative organism. It would be invaluable if we had that, but we would be more focused on bringing the intervention in to play so we can reduce the impact of the particular outbreak in a population.

Mr. TURNER. You mentioned hand-held devices. When I asked Dr. Trent the question earlier, I was envisioning devices that had a broader use than just detecting some of the traditionally known biological agents that are cause for concern. This would be something that would have a dual use capabilities, be diagnostic in nature, and be available to hospitals, doctors,—something that might

be placed in the offices where that kind of diagnostic tool would quickly give a diagnosis. Is that an area that is worth looking into, or worth doing a little research on?

Mr. HENDERSON. I said "hand-held," and really we are talking about portable diagnostic tools that are there at the point of service. You are seeing a person who is ill and potentially you could confirm that they have a particular causative organism, and you know it at the point of service. That is an ideal situation. The CDC clearly would want to work with any partners that are developing this technology, and we have. We continue to do it today.

Mr. TURNER. So there are people out there who are trying to develop that?

Mr. HENDERSON. Lawrence–Livermore. There are a number of labs that we are working with to look into these technologies. Yes.

Mr. TURNER. The second issue that I raised was once the pathogen is identified by genetic signature, whether anyone is researching development of a response capability or shortening the time frame for developing an antibody or response to a given biological agent? Are we still on this long track of developing these vaccines? As you know with Project BioShield, once we found the vaccine, then we are going to spend money to produce it.

I am referencing the gap between detection of a dangerous pathogen and response—how quickly we can develop a response. Are we conducting any work in that area?

Mr. HENDERSON. I have to say, to defend my colleague Tony Fauci at the National Institutes of Health, I always told him I would talk about BioShield in a very positive way, because it is very positive. I think it holds out great hope for us to be able to rapidly develop the countermeasures that we might need to deal with the types of threats and emergencies that we can predict we would have to deal with in a very, very fast manner.

But if you look at diseases like SARS, where there still is no treatment for SARS, we rapidly were able to confirm what the causative organism was. That helps us determine the type of supportive therapy that we would need to provide for the patient, so that we could at least assure they would not die from the particular illness. I think all of our response strategies are looking at the same things that you are offering here, is that how can we rapidly detect what the organism is and then bring about the delivery of the countermeasure as rapidly as possible so you do not have severe illness and death. Everything we are doing is to try to minimize those time lines.

If you asked me specifically what are we doing, we are working with NIH in trying to push BioShield to the full distance we think it needs to travel to help us in that respect.

Mr. TURNER. When you mentioned BioShield, I caught in your inflection your acknowledgement that it does not deal with the development or identification of a response. BioShield applies after a response is identified—it deals with mass production of the response. What I want to know is what kind of research, what kind of investment are we making, whether through CDC or NIH or, Ms. Heinrich, any areas that you research, what kind of investment are we making to try to shorten that time frame between the detection and the development of a response.

Mr. HENDERSON. Mr. Turner, can we get back to you in writing with a response?

QUESTIONS AND RESPONSES SUBMITTED BY JOSEPH HENDERSON

Question: 1. **Are we doing any research to try and shorten the time frame for the development of an antibody or a response to a given biological agent? Or are we still on this long track of developing these vaccines? I am talking about the middle piece between the detection of a dangerous pathogen and the determination as to what you do to counteract it. Are we doing any work in that area?**

Answer: 2. Combating emerging infectious disease is a long term process that requires continuous research and scientific development to identify appropriate countermeasures to prevent and treat illness. An important piece of the long-term model is the development of vaccines and drug therapies to fight emerging infections. However, the development of countermeasures can be a long process. Take SARS as an example. CDC was able to identify and type SARS within a relatively short period of time (a matter of weeks). However, the development of a vaccine is a much slower process that involves complicated, time consuming scientific processes which may not produce a viable biological countermeasure for quite some time.

In the absence of a drug or vaccine, several strategies that can be implemented immediately have been developed to limit the effects of a disease on the population. Between the point at which an illness is identified and a countermeasure or cure is developed, the key to protecting the public's health lies in effective interventions, such as infection control, supportive therapies and containment strategies, to prevent the disease's spread and limit the damage that it can do.

In this short-term time-frame, CDC engages in a variety of activities to prevent the rise of illness in the population and to stem the spread of infectious diseases. Once an infectious disease emerges, CDC utilizes epidemiology to type the disease (its strain) and to identify its cause, source, and mode of transmission. Once this information is ascertained, CDC establishes treatment guidelines for those who are ill and containment or infection control guidelines to prevent the spread of the disease to additional populations. In cases where countermeasures do exist, CDC deploys appropriate medical supplies (medicine, vaccine, etc.) to localities for distribution.

Again, we can take SARS as an example of the use of effective epidemiology and infection control practices to illustrate the benefit of such strategies in the absence of biological countermeasures. Upon the identification of the cause of SARS and an investigation into its mode of transmission, CDC was able to implement highly effective infection control measures (including the monitoring of international passengers, use of information pamphlets to those entering the U.S. from affected countries, standard infection control practices such as hand hygiene in hospitals, schools and homes around the nation) that kept the disease at bay in the United States.

In time, we do expect that biological countermeasures will be developed to combat SARS. However, in the meantime, we will continue to rely on public health measures to combat the re-emergence and spread of SARS.

Mr. TURNER. That would be fine, but I want to know, does that answer mean that we are not doing anything? Or does it mean that you are just not aware of it? Or are you going to ask somebody else? What does it mean?

Mr. HENDERSON. I am just not aware of it. I would have to ask my colleagues at CDC. I want to give you a definitive response because I believe there is research, but I do not have the particulars to talk about today.

Mr. TURNER. Ms. Heinrich, do you have knowledge of any of those efforts?

Ms. HEINRICH. From our previous work, we know that there are a number of efforts underway at NIH at the National Institute of Allergy and Infectious Diseases. There is a lot of basic research that is going on to really understand the immune system and the response to various pathogens. What I think you are asking is when we have had a disease outbreak such as SARS, is it possible to ramp-up both the public and the private sector research capabili-

ties to actually identify antidotes that could be useful in the treatment and care of people that have this particular infectious disease.

I think that using SARS as an example, it was really quite phenomenal to see the work that went on internationally, globally, in identifying the disease agent, as well as at CDC. And then how that information was actually used by labs within NIH, certainly, to begin to try to identify substances that in fact could be helpful in the treatment of SARS. But I do not think there is an answer to your question. I really think it is going to be highly variable based on the disease agent, to be quite honest.

Mr. TURNER. I am just looking for the development of that response capability. My distinct impression is that capability does not exist in the public or the private sector. If we are going to fight bioterrorism in the years ahead, we must have a lab fully-funded somewhere with competent people who can deal with that. I do not really think it is there, and if any of you are aware of its existence in the public or private sector, I would really appreciate the information.

Mr. SHADEGG. I appreciate the gentleman's questions, and would turn now to Mr. Shays for a second round.

Mr. SHAYS. Thank you.

I did not ask specifically a question I want on the record, and I would like each of you to answer. The syndromic surveillance system, it is something you think makes sense? Should we be investing a lot of money in it or not? I would like each of you to tell me what you think.

Mr. HENDERSON. Syndromic surveillance, it is a good question. It is one of those programs that we find in some jurisdictions it works very well. In other jurisdictions, it doesn't.

Mr. SHAYS. Is it more the urban areas that it works better, where you have more concentration of people?

Mr. HENDERSON. I think it really depends upon the people who are standing up the system; the types of syndromes they are looking to report; the reporting entry points; and are they willing to put forth the effort to assure that they can capture the information and put it into the system, and then maintain that level of effort over time.

We have even seen some jurisdictions where they made an investment in syndromic surveillance, but at this point it is a waning thing. They just don't continue to see it as being valuable. So we have a program at CDC where we are going out evaluating the syndromic surveillance systems to see where in fact we find value, what are their success factors, and maybe that will help identify what is really needed to stand up a syndromic surveillance system.

Mr. SHAYS. Thank you. Anybody else care to answer, express an opinion? Yes, sir.

Dr. TEMTE. I believe syndromic surveillance is very important in the practice of usual clinical medicine. In that, the information flowing from syndromic surveillance can inform clinicians about usual trends out there. I agree entirely with Mr. Henderson in terms of it depends on what we are looking for and what population. But things like syndromic surveillance for influenza-like illness are invaluable because they inform us when influenza is in the community. It informs us when we can expect hospitals to be terribly crowded. It informs us about appropriate care, because we know that when flu is around, it really narrows down the diagnosis of patients that are presenting with fever and a cough.

Mr. SHAYS. Thank you. Dr. Platt?

Dr. PLATT. This is a concept that makes every kind of good sense. We really have to do the hard work of understanding when and under what circumstances it provides information that is useful. Then I think we have to make the second decision about where to spend scarce healthcare and public health dollars, because the support that goes to syndromic surveillance or other surveillance systems is support that is not going to many other critical needs. We only started this conversation seriously a couple of years ago, and I think we will be in a much better position to answer your question in a year or two.

Mr. SHAYS. Thank you. That is very helpful. Thank you all.

Mr. SHADEGG. I want to thank all the members of our panel. This has been a very informative discussion. We certainly appreciate your time and your thoughtful testimony.

We stand adjourned.

[Whereupon, at 4:45 p.m., the subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMMITED FOR THE RECORD

ADDITIONAL MEMBER STATEMENTS

PREPARED STATEMENT OF THE HONORABLE SHELLEY BERKLEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEVADA

I would like to thank Chairman Shadegg and Ranking Member Thompson for holding this important hearing to assess our nation's bioterrorism preparedness and to investigate what further steps are needed to ensure our state and local health officials are adequately prepared to respond to a possibility that was unthinkable not that long ago.

Even before September 11th, we were concerned about the state of our nation's health infrastructure. Of particular concern were shortages of nurses, the availability of necessary technology, the lack of adequate disease surveillance protocols and a generally overburdened hospital system nationwide. September 11 th woke our nation to the fact that we have enemies ready and willing to take dramatic and unconventional action against the United States. This realization brings our public health care crises into an even greater focus.

How would a fragile public health infrastructure respond to a disaster involving mass casualties? A terrorist attack demands a skilled and prepared workforce working within a broader public health infrastructure that requires the tools to tackle such a tragedy. Our country's first responders are on the front line of homeland security and our government is taking steps to ensure their preparedness and protection in the event of an attack, but it must be recognized that our nation's hospitals are in the same chain as our first responders when it comes to reacting to an attack. In fact, our hospitals are an essential link in that chain and must be adequately funded to meet potential challenges.

This past August I had the opportunity to hear from the University Medical Center (UMC) in Las Vegas, Nevada, on their terrorism concerns. UMC is the largest public hospital in Nevada. In fact, UMC serves a 10,000 square mile area covering parts of Nevada, California, Arizona and Utah. This amounts to a service population of 1.5 million residents, plus the 35 million visitors to Las Vegas every year. Additionally, UMC is the only freestanding trauma center west of the Mississippi River. If a bioterrorist attack was to occur in Las Vegas or anywhere in the region, UMC would be on the front lines. However, under our federal homeland security programs, public hospitals like UMC are neglected. Public hospitals are excluded from receiving the resources they need by narrow funding fonnulas and a lack of recognition that they too are first responders.

In August, the Department of Homeland Security held Operation Determined Promise 2003, the nation's largest bioterror drill to date, in Southern Nevada. Federal, state and local agencies participated in an event to test their responses to a possible bioterrorist attack on Las Vegas. While this successful event focused on the vital ability of our traditional first responders to react to such an attack, UMC pointed out a few important factors that were not adequately addressed.

First, much of the concern during the drill was about decontamination measures "in the field," with very little concern focused on decontamination "on-site." In other words, funding and training has been focused on protecting those working where the contamination is first released, but not enough has been focused on the ultimate destination of those contaminated, the hospital. In a biological attack our nation's health workers will be among our first responders, and we will be relying on them to treat those affected and to prevent any potential spread of disease or contamination. On-site decontamination equipment and facilities are important to protect our doctors and nurses, and ultimately our communities.

Second, public hospitals are essentially excluded from our federal homeland security funding programs. Currently, homeland security grants administered by the De-

partment of Justice and Department of Homeland Security are very strict about what entities a state may award those funds. These approved entities do not include public hospitals. There is a pressing need for our federal homeland security grant programs to be expanded and made more flexible to include our vital public hospitals.

As we have heard from our first responders, such as police and firefighters, interoperability of communications must be enhanced. UMC also has an essential need for improved communications between the hospital and the various levels of first responders, including police, fire and emergency medical personnel, in the event of an attack. Additionally, UMC requires personal protective equipment, special isolation capacity, security-related technology, mobile hospital facilities, increased training and specialized personnel. Under our current grant programs, these needs go virtually unaddressed.

Again, thank you Mr. Chairman for this hearing and for the opportunity to speak to what I feel is one of the most important homeland security issues our nation faces. I look forward to working with you and the Committee to ensure that our public hospitals are adequately funded and that we avoid depleting existing resources used for the everyday treatment of patients in order to meet our preparedness needs as we move forward to meet our nation's security challenges.

UNITED STATES GENERAL ACCOUNTING OFFICE
Washington, DC, November 14, 2003

Hon. JOHN SHADEGG
Chairman, Subcommittee on Emergency Preparedness and Response, Washington, DC 20515

DEAR CHAIRMAN SHADEGG: Thank you for the opportunity to appear before the Subcommittee on Emergency Preparedness and Response hearing entitled "Disease Surveillance Systems: How Can They Help Prepare the Nation for Bioterrorism?" on September 24, 2003. Subsequent to the hearing, you forwarded additional questions from Representative Jim Turner, the Ranking Member of the Select Committee on Homeland Security. Here are Mr. Turner's questions and my response.

(1) **What role does international disease surveillance play in detecting bioterrorism or naturally-occurring diseases? Could it also be very useful for detecting terrorist experimentation with bioweapons? What work is CDC doing with the World Health Organization or other international organizations to promote international disease surveillance?**

(2) **What Department of Defense programs exist for disease surveillance and how are these being integrated with CDC? How do you see the DOD programs fitting into civilian surveillance programs? How can they be coordinated with civilian systems? Is there ny unnecessary duplication of capabilities?**

Unfortunately, I am not able to provide specific answers to most aspects of these questions now. At the request of Senator Norm Coleman, Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, United States Senate, we have recently begun a study of both U.S. and international infectious disease surveillance systems. Among other issues, the study will examine the coordination between different surveillance systems, including the CDC and DOD systems.

I can tell you that the CDC works closely with WHO to improve international diseases surveillance capabilities. CDC is a major partner in WHO's Global Alert and Response Network (GOARN) and provides resources (e.g. staff, laboratory materials, etc.) and expertise to WHO in epidemiological investigations. For example, CDC played a major role in the global response to SARS, providing technical consultations and deploying staff overseas. On an ongoing basis, CDC also serves as a technical consultant to ministries of health on projects that address disease surveillance. Through its Field Epidemiology Training Programs, the Epidemic Intelligence Service, and other programs, CDC has also supported research and public health education on disease surveillance around the world.

Sincerely yours,

JANET HEINRICH,
Director, Health Care, Public Health Issues

DR. PLATT RESPONSE TO ADDITIONAL QUESTIONS FROM THE HOUSE SELECT COMMITTEE ON HOMELAND SECURITY, SUBCOMMITTEE ON PREPAREDNESS AND RESPONSE

Subcommittee Ranking Member-Bennie G. Thompson

Question: **1. In response to a question from the subcommittee regarding strategies for improving disease surveillance among local practitioners, you briefly described a potential solution that would utilize existing health plans to provide better communications and interaction with the public health syStem.**

Please briefly expand upon this solution, specifically identifying any strategies that might benefit from legislative action at the State or Federal level.

Congressional action may be needed to stabilize and increase funding for advancing a health information infrastructure that supports early detection and improved interactions between the private and public sectors. Efforts at the State and Federal level that support current health information technology initiatives and enhance the dissemination of electronic health records and other health communications rely on stable funding from Federal or state demonstration projects and/or financial incentives to build compatible information systems. In addition, promulgating the development of IT standards will be instrumental in transforming health care generally, and improving our ability to detect unusual outbreaks of disease and bioterrorist threats.

Second, it will be important to ensure sufficient funding to allow state and local departments of health to fully implement the technology improvements that are being developed as part of the Public Health Information Network (PHIN), including the National Electronic Disease . Surveillance System (NEDSS), and rapid public health communications systems.

Third, it will be worthwhile to create incentives for software vendors to incorporate public health surveillance and reporting capabilities into their products. These reporting capabilities should be under the control of the clinicians and health plans, so that they can modify their reporting to accommodate state and local reporting needs as well as their own needs. My partners and I believe there is special value in enabling providers and health plans to report routinely at various levels of detail, including simply the counts of new episodes of illness that are the basis of the National Demonstration Program I described in my testimony and refer below to the model we have developed to provide high level protection to individual level data, by having the health plans retain possession of individual level data unless there is a need to evaluate a specific apparent cluster of illness.

Subcommittee Member-Dave Camp

Question: **1. In your written testimony you discussed Harvard's National Bioterrorism Surveillance Demonstration Program. Does your program receive any intelligence information or threat assessments from the federal government to help focus or supplement your surveillance?**

Our project does not receive intelligence information or threat assessments. We recommend this information be provided to public health agencies, which can then lower the threshold above which they respond to unusual clusters of illness in specific locales. This would allow public health officials to evaluate clusters of illness in a particular area of interest that they might otherwise choose not to evaluate because of other priorities.

We have asked that our partnering public health agencies "set the threshold" for detecting possible outbreaks according to their needs. One state may want to look more closely at an alert that statistically is expected to occur twice per year. Others may want to set the threshold very high (once in two years) or very low (once in a month). Intelligence or threat estimates could prove useful in establishing a more appropriate threshold level as threats are recognized.

Question: **2. Have you encountered difficulties in acquiring the necessary data from some hospitals and community health centers that do not have adequate or appropriate computer systems or technology? Is any progress**

being made to facilitate sharing this information? What recommendations can you give to improve real-time data reporting from these facilities?

As mentioned above, adoption of an electronic medical record that captures patient level information during the delivery of care is a key requirement to performing "real-time" assessments.

Our project is based on health plans, clinicians, and public health volunteering to participate in the demonstration program. The participating groups in Texas began their participation due to the efforts of a local public health official interested in developing their capacity to support improved disease surveillance.

We are in discussion with community health centers that have electronic medical records and an interest in supporting this work. Community health centers serve both a "known" and a "dropin" population presenting unique challenges and opportunities for improving our surveillance net. Many academic centers sponsor community health centers and currently have, or are in the process of implementing, an electronic medical record system. These centers are good candidates for joining our program.

Because our system primarily focuses on ambulatory care data, we have not actively sought out participation from hospitals. The advantage of this is that sick individuals may seek care sooner in ambulatory settings than at hospitals or emergency rooms. Additionally, our system benefits from knowing how many people are at risk for illness in each zip code (members of a health plan); this improves our analytical accuracy for detecting a possible outbreak.

We have developed a detailed plan to evaluate the relative value of a wide variety of data streams for bioterrorism surveillance (e.g., nurse call centers, ambulatory care, emergency rooms, hospital admissions, pharmacy, laboratory and radiology). However, we currently do not have funding to carry out this evaluation.

Full Committee Ranking Member-Jim Turner

Question: **1. How do we avoid "false alarms" from syndromic surveillance systems? Too many of these could undermine the public's confidence and might desensitize them to an actual attack. How will followup investigations be conducted so as not to overly alarm the public?**

There is a tradeoff in setting the "alarm threshold" to find signals at the earliest possible time while avoiding too many false alarms. Our system allows public health officials to set the alarm threshold that best meets their local needs. Because our system alerts public health and the health plan simultaneously about an unusual number of illnesses, there is an opportunity to use the full electronic medical records to determine quickly and at minimal cost if an alert is a false alarm.

One of our evaluation approaches to helping health departments set the alarm threshold has been to use known infectious disease clusters that have occurred in the past and use this data to test our current system. The combination of these tests with the actual experience of investigating unusual events will mitigate some of the negative impact of false alarms.

Question: **2. How is the privacy of the individual patient's medical information ensured in your systems? Do you know if other surveillance systems have considered privacy issues in their development?**

Privacy of the individual patient's medical information is a key feature of our program. We have avoided many problems that other surveillance systems must address because our participating health plans do not share the confidential health information of their members, unless there is specific evidence of a cluster of illness that requires follow-up by public health officials. We accomplish this by having the health plans routinely report only the number of people with new episodes of illness. This is sufficient to alert health departments about potential problems and to trigger follow-up. Investigation of specific events has been standard public health practice for many years.

Our model thus provides a new method to balance individuals' right to privacy and the public health system's need to investigate a likely threat.

It is my understanding that other surveillance systems have considered privacy issues in different ways.

QUESTIONS AND RESPONSES FROM DR. JONATHAN L. TEMTE TO MEMBER'S WRITTEN QUESTIONS

Response to Subcommittee Ranking Member Bennie G. Thompson.
Re: Strategies for improving disease surveillance among local practitioners

i: Enhanced medical education on disease surveillance

At present, there is little guarantee that medical students and/or medical residents in any specialty receive meaningful training in the purpose, role, and prac-

tices of the public health system in the United States, including issues of disease surveillance. Accordingly, the patient-focused healthcare system and the public health system often function in parallel instead of interactively. A basic understanding of population approaches to health, emergency response, and disaster preparedness is an essential component of homeland security. For example, a recent study conducted by the American Academy of Family Physicians has indicated that prior training of clinicians in bioterrorism preparedness was associated with significant enhancement of comfort and communication around potential bioterrorism events.

In 2002, the Accreditation Council for Graduate Medical Education (ACGME) mandated that all graduate medical education (i.e., residency) programs in the United States must assure that their trainees attain competence in six areas:

- Patient Care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health
- Medical Knowledge about established and evolving biomedical, clinical, and cognate (e.g. epidemiological and social-behavioral) sciences and the application of this knowledge to patient care
- Practice-Based Learning and Improvement that involves investigation and evaluation of their own patient care, appraisal and assimilation of scientific evidence, and improvements in patient care
- Interpersonal and Communication Skills that result in effective information exchange and teaming with patients, their families, and other health professionals
- Professionalism, as manifested through a commitment to carrying out professional responsibilities, adherence to ethical principles, and sensitivity to a diverse patient population
- Systems-Based Practice, as manifested by actions that demonstrate an awareness of and responsiveness to the larger context and system of health care and the ability to effectively call on system resources to provide care that is of optimal value

None of these competencies appropriately addresses an understanding of public health function or the interaction of public health resources within traditional patient care models.

Proposed Enhancements:

1. Work with the American Association of Medical Colleges [AAMC] to support curriculum development and implementation into all U. S. based medical schools. Please refer to information available at *http://www.aamc.org/preparedness/start.htm* for information on initiatives already underway at the AAMC.
2. Work with the Accreditation Council for Graduate Medical Education [ACGME] to expand the current six core competencies to include a 7th competency on public health function, emergency preparedness and disaster response.
3. It may be the appropriate time for Congress to commission an in-depth strategic report—similar to the Flexner Report of 1910—that addresses the gap between public health practice and individually oriented medical care and makes recommendations as to the required training components and competencies that should become incorporated into the training of both public health professionals and medical professionals.

ii: Improve public health system interaction with local practitioners

This is an area where there has been little directed study. Accordingly, recommendations on improving health system interactions are limited. A recent Agency for Healthcare Research and Quality (AHRQ) funded evidence report on training clinicians for response to bioterrorist attacks (available at *http://www.ahra.gov/clinic/tp/biotrtp.htm*) concluded that there existed only modest evidence about effective ways to train clinicians as to how to respond to bioterrorist attacks.

There are, however, several success stories of ongoing interactions between public health systems and local practitioners. Perhaps the best example is the U. S. Influenza Sentinel Provider Surveillance Network, which exists as a cooperative effort between the Influenza Branch at the CDC and approximately 1,600 volunteer primary care clinicians scattered across the United States. This low-cost surveillance system has functioned successfully over the past 30 years, informing public health professional *and* clinicians on the presence and intensity of influenza.

Proposed Enhancements:

1. Ensure sufficient and longitudinal funding for continuation and expansion of the CDC's U.S. Influenza Sentinel Provide Surveillance Network. This support requires core support of the Influenza Branch at CDC, support of state influenza surveillance coordinators, and support for primary care liaisons to function as medi-

ators between public health and primary care communities. Such funding also ensures an ongoing system that can function to detect events that share significant features with bioterrorist agents.

2. Enhance funding through the Agency for Healthcare Research and Quality to provide direct research grants for studying effective means of enhancing primary care clinician education and performance in issues relevant to public health and bioterrorism response. It is highly important to evaluate this function of primary care clinicians within the United States—the venue wherein most citizens receive most of their care most of the time.

iii: Provide better understanding of public health processes to local practitioners

There are few opportunities for healthcare providers to interact in meaningful ways with local and state public health professionals. Most interaction currently occur around the mandated reporting of cases of public health interested (usually communicable disease or significant environmental exposures). Few clinicians understand the vital role played by public health agencies in outbreak investigation, disease control, and public education.

Participation in sentinel surveillance—in which the clinician actively detects cases, reports to a central agency, and receives clinically relevant feedback—is a clear example of a means to enhance better understanding of public health function. Participation in influenza surveillance activities is especially beneficial in this regard because response to influenza involves a wide cross section of public health activities: local, regional, national and international surveillance, vaccination policy, utilization of health care facilities, public education. Added benefits lie in the fact that influenza-related activities are extremely clinically-relevant, especially in primary care medicine. Cases of influenza are commonly seen by almost all clinicians and almost every year.

Proposed Enhancements:

1. Provide funding to enhance influenza surveillance and create incentives for the participation of clinicians that will be developed into liaison roles, thus helping to bridge the gap between clinicians and public health professionals. This could be done at state and national levels. A reasonable goal may be two to four surveillance clinicians per each U. S. Congressional district.

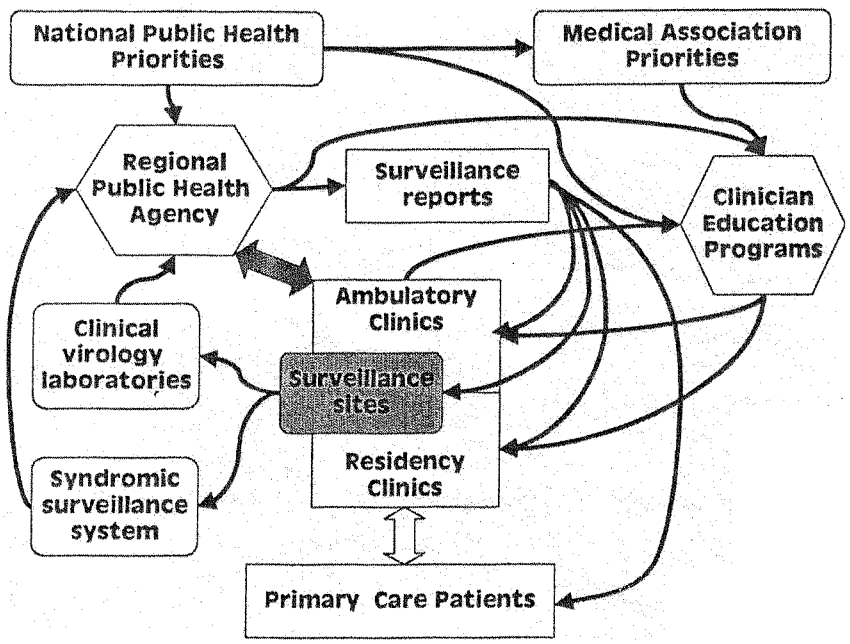
2. Create funded, short-term fellowships in public health for primary care and other interested clinicians. These could take the form of abbreviated "Epidemiologic Intelligence Service" training through the CDC. The goal would be the creation of a cohort of clinicians that would mediate between patient care and public health agendas.

iv: Improve and regularize communications between public health systems and clinicians

There are no systems that currently exist for the purpose of regular communication between public health agencies and clinicians. Information tends to flow to select clinicians regularly (via publications such as MMWR) or irregularly (via local or regional public health alerts). Most information to public health agencies from clinicians occurs in the form of mandated, reportable illness case reports. There is good evidence that many reportable cases go unreported and that action steps taken by public health in response to reports are not communicated back to the clinician.

Ongoing information exchange between public health agencies and clinicians around topics that are clinically relevant can serve to maintain appropriate, bi-directional conduits for communication. Excellent examples of this exchange again are found in functional influenza and respiratory virus surveillance systems such as the U.S. Influenza Sentinel Provider Surveillance System or the National Respiratory and Enteric Virus Surveillance System (*htp://www.cdc.gov/ncidod/dvrd/revb/nrevss/rsvtre1.htm*). These systems are currently limited, however, in the amount of information flow to clinicians.

A proposed, complete surveillance system is illustrated below demonstrating not only reporting of surveillance information to public health agencies and feeding back clinically-relevant information to clinicians, but also serving as a means to rapidly provide clinicians with "Just in time" information and education and encouraging clinicians to report "unusual" events.


National Public Health Priorities
Medical Association Priorities
Regional Public Health Agency
Surveillance reports
Clinician Education Programs
Ambulatory Clinics
Clinical virology laboratories
Surveillance sites
Residency Clinics
Syndromic surveillance system
Primary Care Patients

One key deficiency is the lack of a reliable and redundant communication pathways (e.g., e-mail addresses, fax numbers, telephone numbers) of all clinicians.

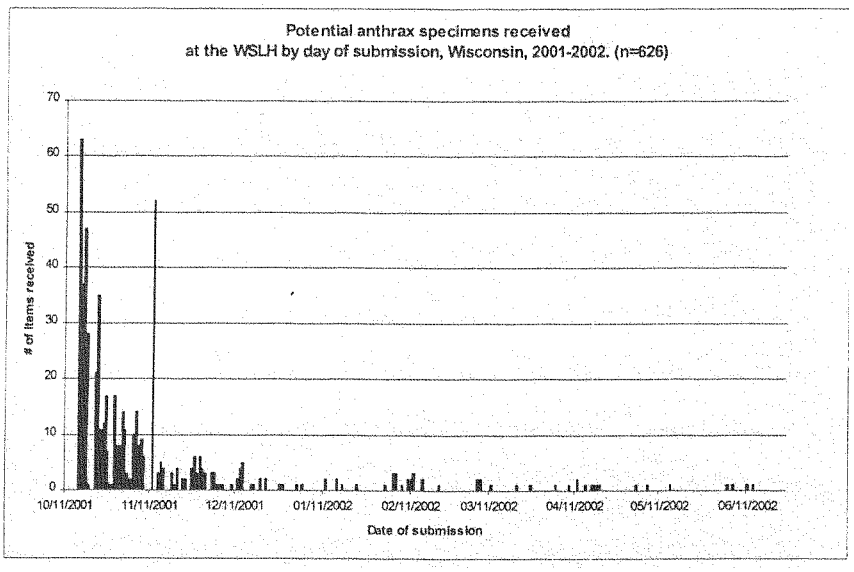
Proposed Enhancements:

1. Create a national priority, coupled with adequate funding, to establish systems of common disease sentinel surveillance, which could be utilized for special circumstance surveillance (e.g., bioterrorism). Such a system is ultimately dependent on the availability and flow of clinically relevant information to clinicians. A potential first step would be to provide funding to demonstration and evaluative projects involving primary care, practice-based research networks. Mechanisms for such funding currently exist through the Agency for Healthcare Research and Quality.
2. Legislate mandated reporting of each clinician's e-mail address, fax number and telephone number as a part of state and territorial level licensure procedures to maintain direct and redundant conduits of communication.

Response to Subcommittee Member Dave Camp.
Re: Tbe role of primary care physicians in alleviating the fear and panic accompanying bioterrorism threats and attacks

Whereas the subcommittee hearing focused on the detection of and surveillance for agents of biological terrorism, an equally important component of response exists in the control of panic. To quote from Sidell FR et al: *"The real force multiplier in BW (biological warfare) is the panic, misinformation and paranoia associated with it."* [Sidell FR, Patrick WC, Dashiell TR. Jane's Chem-Bio Handbook, Jane's Information Group, Alexandria, VA, 1998]. And so it goes with bioterrorism.

In the days following the October 2001 anthrax attacks, wholesale panic gripped the American public. As a family physician practicing hundreds of miles from the nearest case of inhalational anthrax, I was amazed at the number of questions regarding white powder that patients brought to our clinic. Likewise, the Wisconsin State Laboratory of Hygiene was inundated with samples of powder for anthrax testing (see figure). The

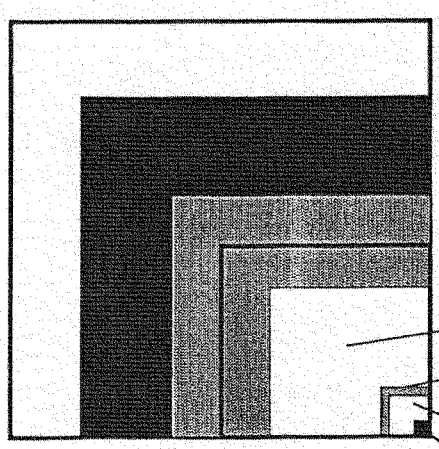

Potential anthrax specimens received
at the WSLH by day of submission, Wisconsin, 2001-2002. (n=626)
# of items received
70
60
50
40
30
20
10
0
10/11/2001
11/11/2001
12/11/2001
01/11/2002
02/11/2002
03/11/2002
04/11/2002
05/11/2002
06/11/2002
Date of submission

temporal pattern of specimens submitted for testing also describes panic well. As the general public was reassured, the level of comfort increased, and panic, hysteria and fear declined. To manage bioterrorism, one needs to focus on the terror as much as on the detection and treatment of bioterrorism related disease.

To best understand the role of primary care physicians in countering the fear and panic associated with bioterrorist threats and events, one must first understand the structure and function of the U.S. medical system-often referred to as the ecology of medical care and the widespread location of primary care physicians. The ecology of medical care in the U.S. has been relatively stable for the last 40 years. Each month, approximately 32.7% of Americans consider a medical care visit. Of those seeing a physician, more than half see a primary care physician.

The Ecology of Medical Care

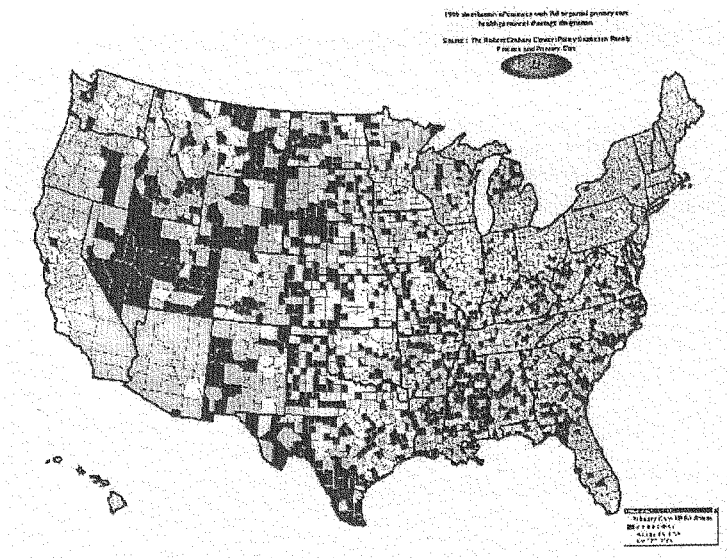
Green LA. Fryer GE Jr. Yawn BP. Lanier D. Dovey SM. The ecology of medical care revisited. *New England Journal of Medicine. 344(26):2021-5, 2001 Jun 28.*



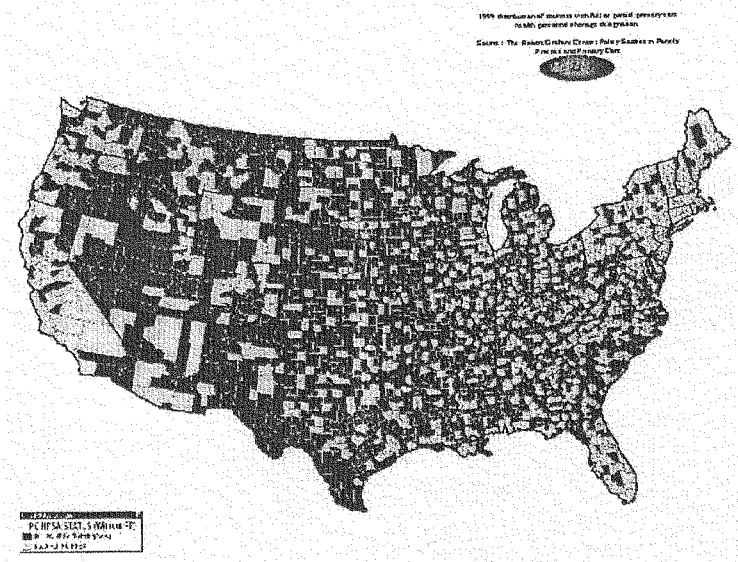
It is estimated that family physicians evaluate and manage about one billion medical concerns each year in the United States. Many of these concerns are best addressed with reassurance, education and anticipatory guidance. Primary care physicians, due to basic core values, provide longitudinal care to individuals and communities across the spectrums of age, gender, ethnicity and race, and affected organ system. A central tenet of the primary care physician's relationship with his/her patients is trust. Accordingly, it is to trusted healthcare providers that patients come with issues resulting from fear.

The widespread location of primary care physicians, and specifically family physicians, is noteworthy. Bioterrorist events have been and will likely be rather limited in geographic distribution. The specific locations of covert bioterrorist events are not predictable, but the venue of fear and panic is incredibly widespread. The graphics on the following page underscore the wide distribution of family physicians in the U.S.

In summary, following a bioterrorism event, or under the threat thereof, individuals with significant fear and panic will greatly outnumber individuals affected with a biological agent. These "worried well" will commonly seek out trusted and available physicians. The essential role of the primary care physician, equipped with appropriate and up-todate ('just-in-time") information, is to use the patient-physicians relationship from which to provide reassurance, education and comfort. Efforts to ensure the future supply of well-trained, competent and compassionate primary care physicians are of paramount important to biological defense and homeland security.



Currently designated Primary Care Health Personnel Shortage Areas
(dark shading: n = 784 of 3082 counties)



Counties that would qualify as Primary Care Health Personnel Shortage Areas if family physicians were removed. (dark shading: n = 2116 of 3082 counties)

Creating Complete Surveillance

Jonathan L. Temte, MD/PhD
University of Wisconsin Department of Family Medicine

modified from a presentation to the

American Medical Informatics Association

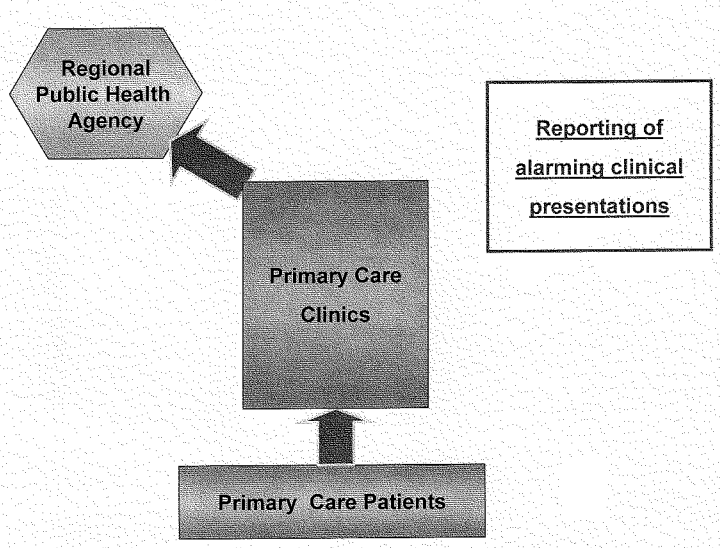
Washington, D.C.

4 November, 2001

Primary Care Surveillance in Bioterrorism Response

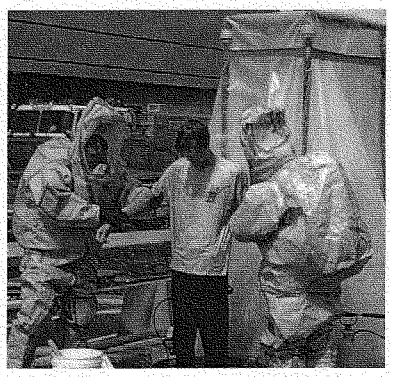
	Covert unannounced unknown location	**Semi-Covert** announced unknown location	**Overt** announced known location
Real	**Chance Detection Surveillance**	**Case Finding Surveillance**	Emergency Response Management
Hoax	"Really Stupid Perpetrator"	**Case Finding Surveillance**	Emergency Response Management

Goal of Training for Response to Rare Clinical Events

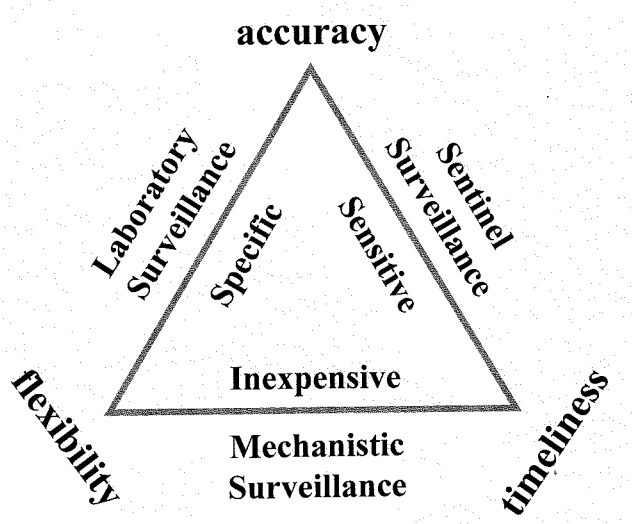


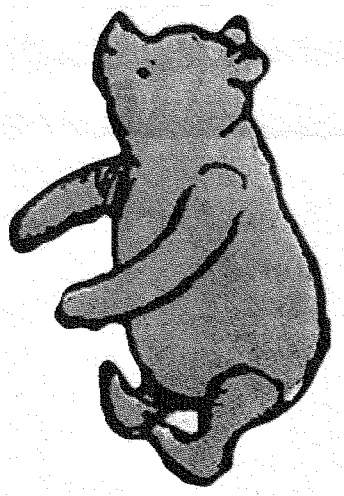
Why Surveillance for Bioterrorism?

- Rare events
- High Public Health Consequences
- Benefits of 'early detection"



Properties of Surveillance Systems





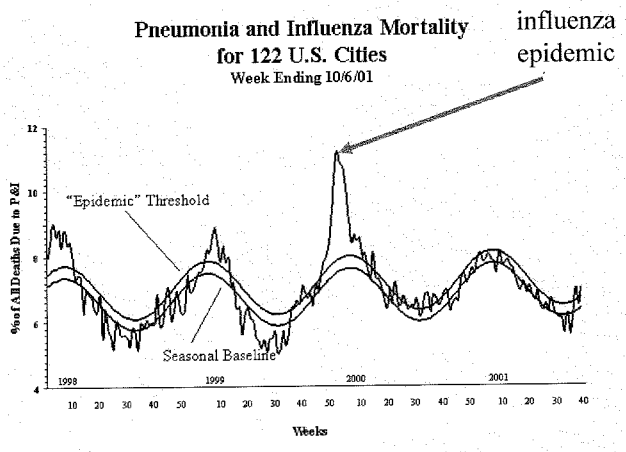
"Pooh," said Rabbit kindly,
"you haven't any brain."
"I know," said Pooh humbly.

- "Winnie-the-Pooh"

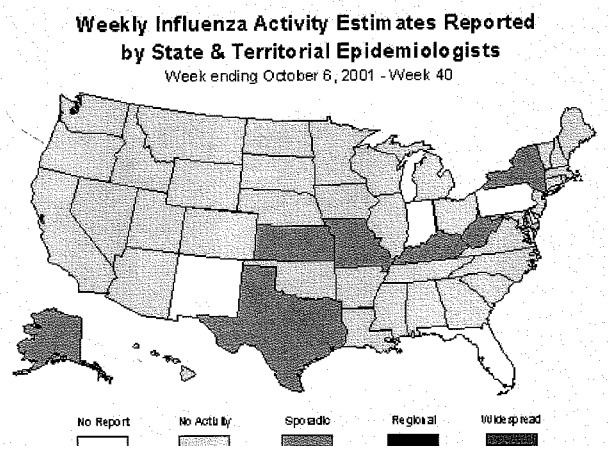
Mechanistic Surveillance

- "Mindless" mining of already collected and/or collated data
  - billing records
  - admission diagnoses
  - death certificates
  - pharmacy sales
  - other creative entities
- Questions and answers are limited by data quality and reasonability of extrapolations
- Can be quick and <u>inexpensive</u>

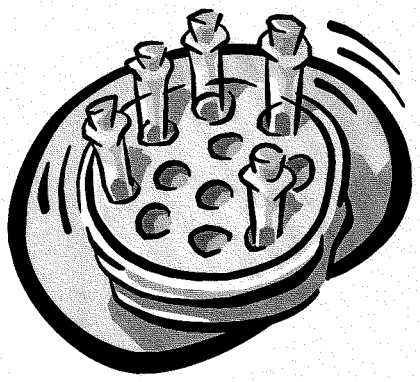
Mechanistic Surveillance Example: CDC's P&I Mortality Index



Expert Surveillance

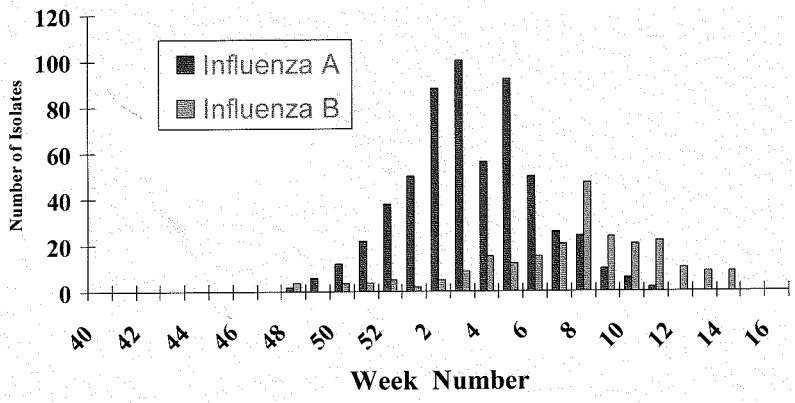


Laboratory Surveillance



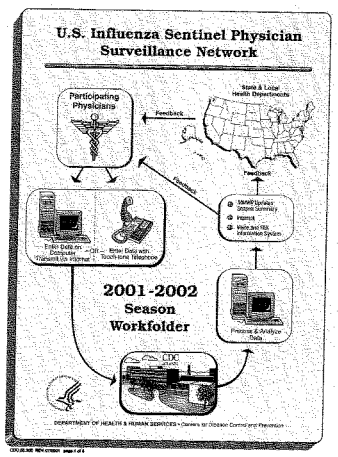
- High Specificity
- Use of "Gold Standard" instead of Proxy
- Time consuming
- Expensive
- Limited Access
- Can distinguish between types of agents

Laboratory Surveillance Example:
Influenza - Wisconsin 2000/2001



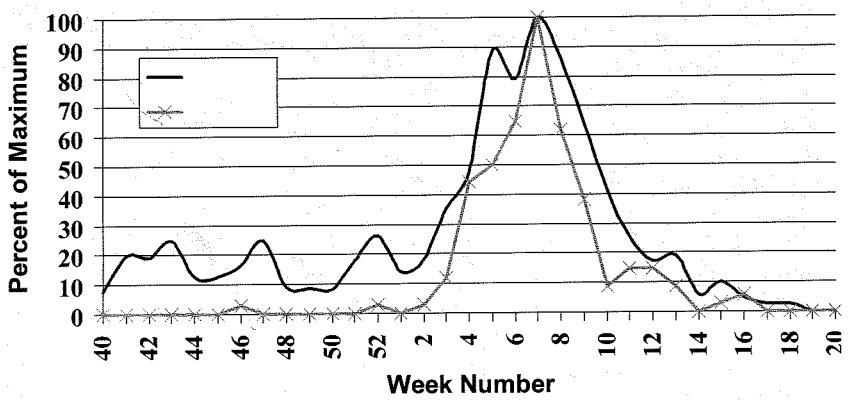
(Data from Wisconsin State Laboratory of Hygiene)

Sentinel Surveillance



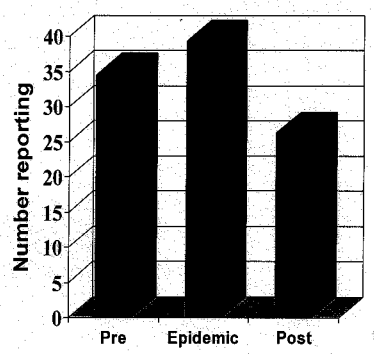
- Sensitive and accurate
- combines criteria with clinical judgement
- can be timely compared to other methods
- can be "enhanced"
- limited by demands on sentinels

Comparison of Wisconsin Influenza Surveillance Systems -- 1998/99



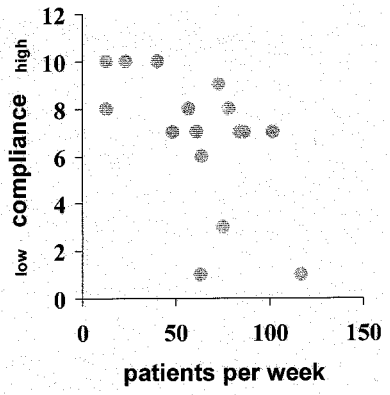
Relationship between Compliance in Influenza Surveillance and Epidemics

- Compliance in making weekly reports related to epidemic timing
  - $X^2 = 33.547$; $P<0.001$
- slight increase during the 9-week epidemic
  - 13.6% increase in reporting
- significant decrease after the excitement
  - 33.1% decline in reporting



Compliance is negatively related to intensity of practice

- 17 family physicians
- patients w/dyspepsia
  - first visits
  - follow-ups
- 12 month study
- rank correlation
  - rs = -0.590
  - $P<0.02$



(Temte & Beasley, J Fam Pract 2001; 50:977)

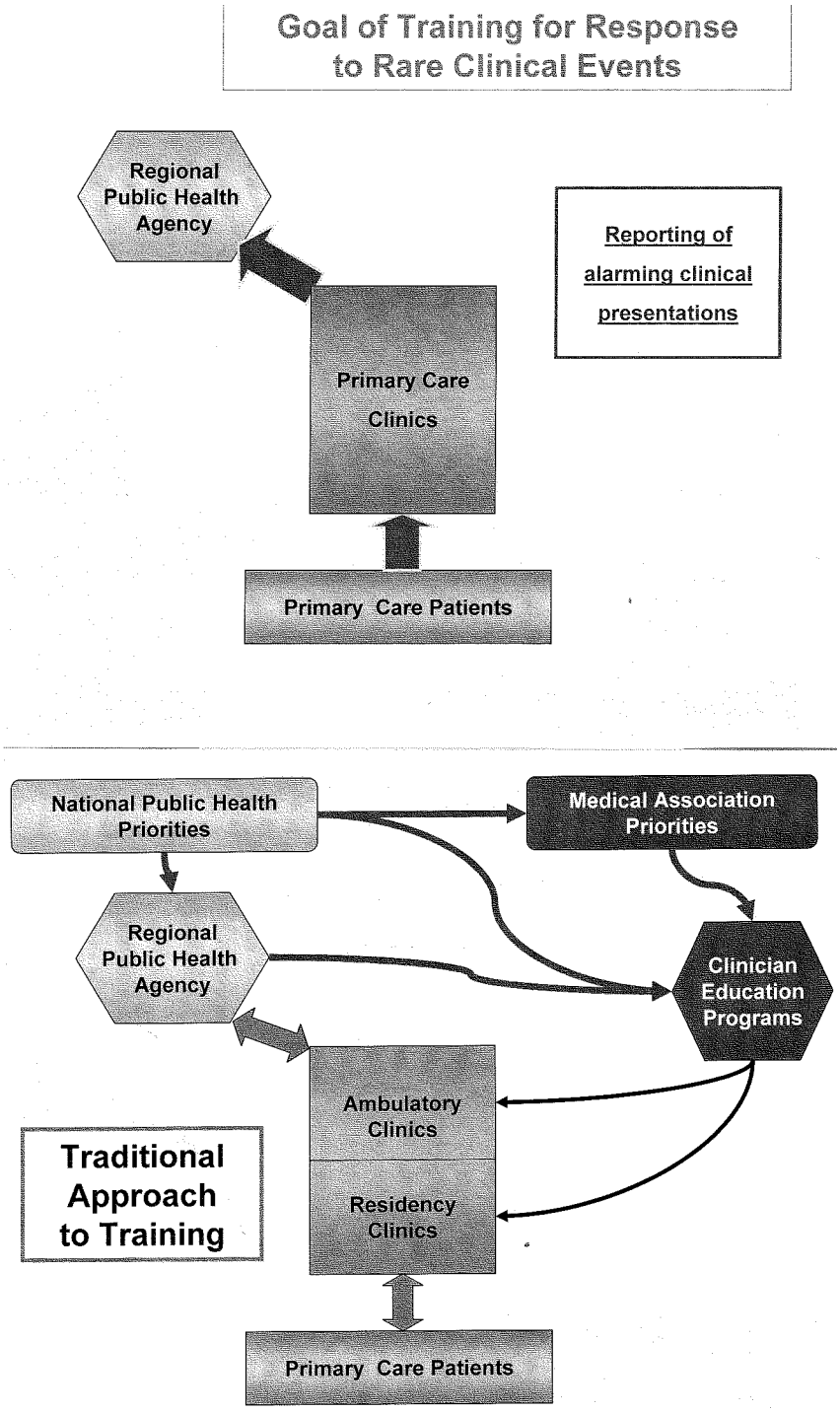
Holy Grail of Surveillance

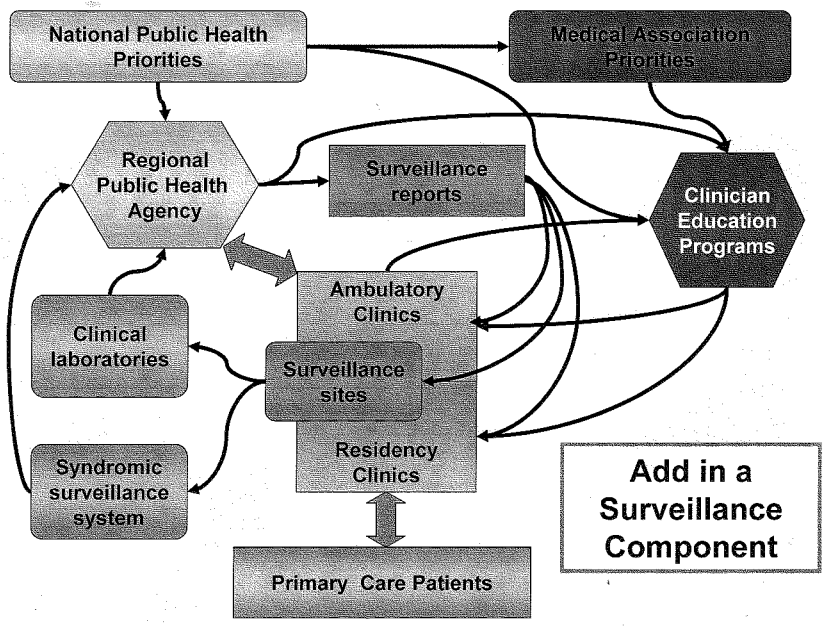
- **Complete Information**
  - **sensitive**
  - **specific**
  - **accurate**
- **Real Time Reporting**
- **Flexible System**
- **Useful**

Creating Complete Surveillance

For Bioterrorism and other rare events of public health significance:

the primary role of surveillance is to set a denominator against which unusual clinical events can be evaluated.

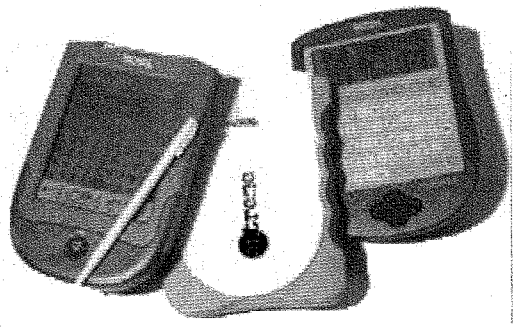

Goal of Training for Response to Rare Clinical Events
Regional Public Health Agency
Reporting of alarming clinical presentations
Primary Care Clinics
Primary Care Patients
National Public Health Priorities
Medical Association Priorities
Regional Public Health Agency
Clinician Education Programs
Ambulatory Clinics
Residency Clinics
Traditional Approach to Training
Primary Care Patients



People

- 2 full-time family physicians per each U.S. Congressional district (n = 870)
  - geographic and demographic distribution
- Paid for 10-20% of their time to be sentinels

Tools

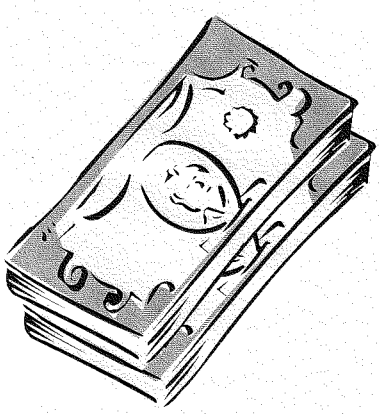


- Hot-linked palm computers
- Daily downloading of surveillance data
- As needed up-loading of surveillance protocols

Partnerships

- Public health agencies
- Health maintenance organizations
- Professional associations

Funding



- Long-term commitment
- infrastructure costs
- personnel costs
  - central office
  - "paid" sentinels
- income from data
  - contacting for studies
  - basic information for MCOs

Estimated Cost:
$20-40 million per year

Needles and Haystacks

The realities of identifying bioterrorism events in medical practice

Jonathan L Temte, MD/PhD

modified from the orignal presented at the

American Academy of Family Physicians
Robert Graham Policy Center
December 13, 2001

The Essential Question

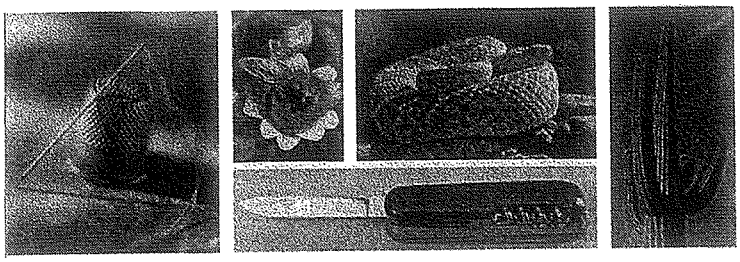
Just suppose that you happen to be rolling around in a haystack and you get stuck by something. Does the fact that you got stuck by something make that something a needle?

Axiom 1:

There are a lot of haystacks

Axiom 2:

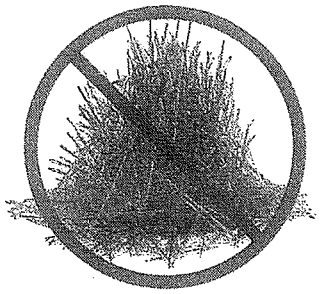
Lots of things are sharp

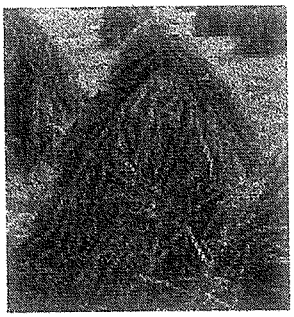


Corollary: most sharp things are not needles

Axiom 3:

Most haystacks are void of needles





Corollary: most haystacks contain only hay

Suppose you wish to set up an early-detection system for Inhalation Anthrax

- **you have an excellent detection tool**
  sensitivity = 95%
  specificity = 95%
- **where should this be deployed ?**

Searching for Cases

	Anthrax +	**Anthrax -**	Total
Test + Criteria +	True Positive	False Positive	**Positives**
Test – Criteria –	False Negative	True Negative	**Negatives**
Total	**Cases**	**Non-Cases**	At Risk Population

Public Policy Perspective

Goal: maximize likelihood of discovering cases
Method: high sensitivity of test

	Anthrax +	**Anthrax -**	Total
Test + Criteria +	True Positive	False Positive	**Positives**
Test – Criteria –	False Negative	True Negative	**Negatives**
Total	**Cases**	**Non-Cases**	At Risk Population

Prevalence insensitive

Clinician Perspective

Goal: maximize likelihood of appropriate care
Method: high positive predictive value of test

Prevalence sensitive

	Anthrax +	Anthrax -	Total
Test + Criteria +	True Positive	False Positive	**Positives**
Test – Criteria –	False Negative	True Negative	**Negatives**
Total	**Cases**	**Non-Cases**	At Risk Population

Some Basic Epidemiology Math

assuming a near-perfect test or clinical criteria and that 1000 cases of inhalational anthrax are mixed into the U.S. population

	Anthrax +	Anthrax -	Total
Test + Criteria +	950	13,500,000	13,500,950
Test – Criteria –	50	256,500,000	256,500,050
Total	**1000**	**270,000,000**	270,001,000

Sensitivity = 0.95 Specificity = 0.95

Some Basic Epidemiology Math

Sensitivity = 0.95 Specificity = 0.95

- **Positive predictive value**

  950 / 13,500,950 = 0.007 %

  (13.5 million case investigations)

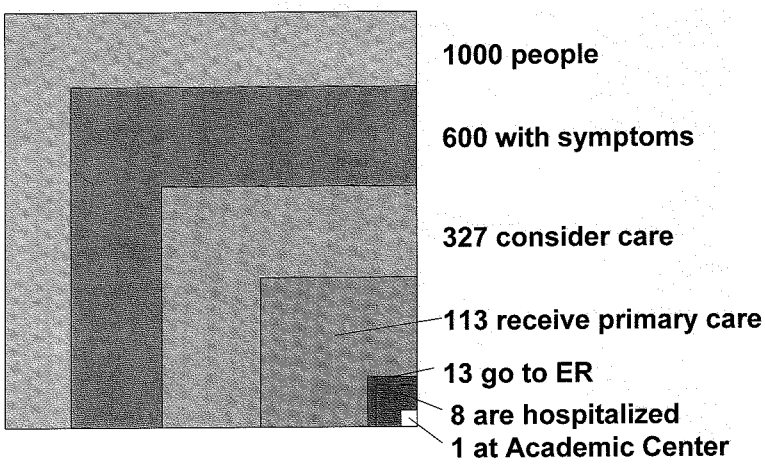
- **Negative predictive value**

  256,500,000 / 256,500,050 = 100%

The Ecology of Medical Care

Green LA. Fryer GE Jr. Yawn BP. Lanier D. Dovey SM. The ecology of medical care revisited. *New England Journal of Medicine. 344(26):2021-5, 2001 Jun 28.*

Out of 1000 people each month in the United States:



Inhalation Anthrax in Patients with Influenza-like Illness

(assume that all positive cases move to the next level)

Location of Patient	Population Size	False-to-True Signal Ratio
Symptomatic in community	30,000,000	**1579**
Considers a Visit	16,350,000	**860**
Primary Care	5,650,000	**297**
Emergency Room	650,000	**34**
Hospitalized	400,000	**21**
Academic Center	50,000	**2.6**

Detection and Diagnosis of Cases

Location of Patient	Timing	Total Mortality	Method of Diagnosis
Symptomatic in community	very early	very low	Chance
Considers a Visit	very early	very low	Chance
Primary Care	early	low	Context
Emergency Room	moderate	moderate	Laboratory, X-ray, CT-scan
Hospitalized	late	high	Specialty Care
Academic Center	late	very high	Autopsy

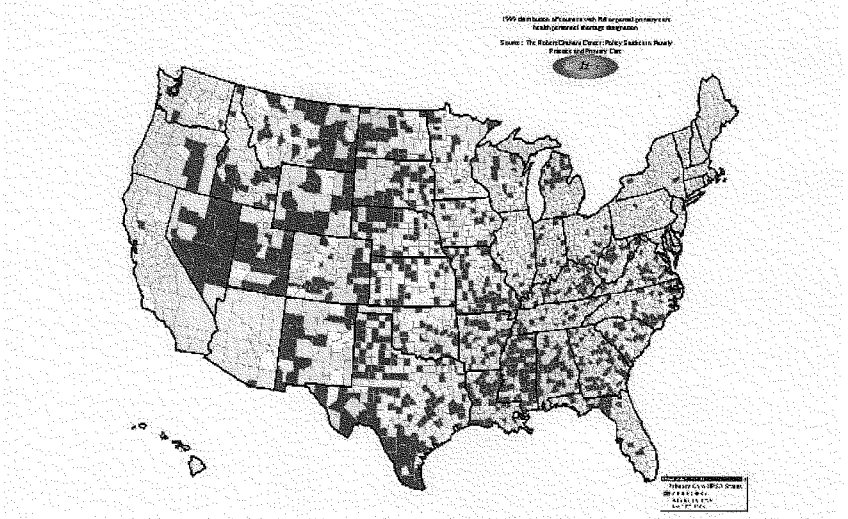
"It is inherently dangerous to set up surveillance systems for early detection of and response to extremely rare events"

This may ultimately enhance the "terror" within bioterrorism

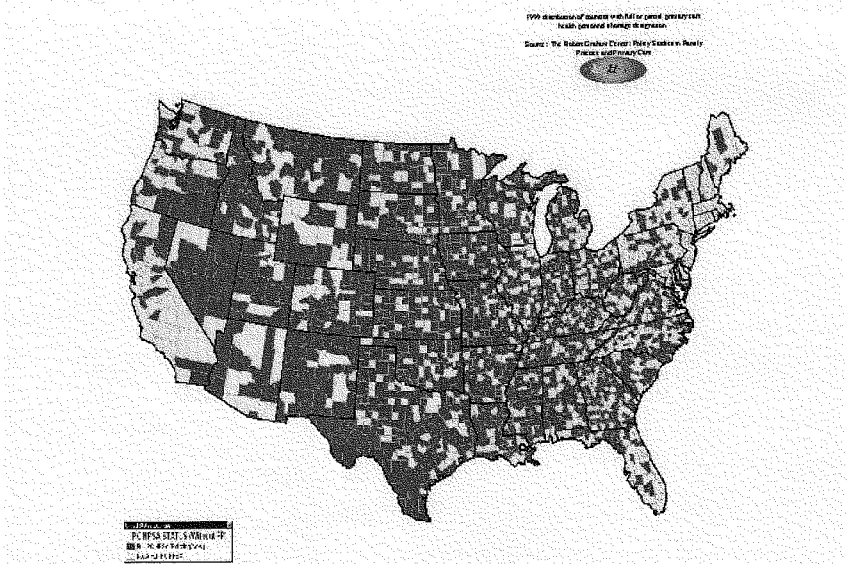
Factors enhancing family practice's role in Bioterrorism Detection and Response

- **Location** - geographically disperse
- **Orientation**: care provided regardless of...
  - Age and gender
  - organ system
- **Contextual Relationships**: continuity of care
  - longitudinal care resulting in trust
  - community centered

Physician Shortage Areas

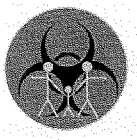


Take away Family Physicians...

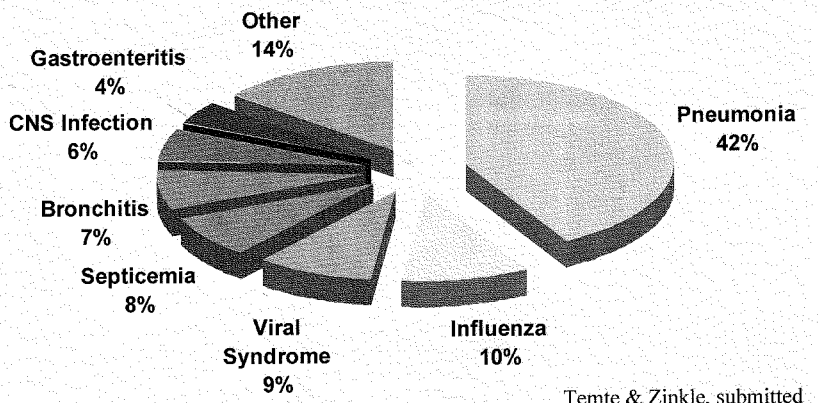


Inhalation Anthrax presented in a very diverse population

- Age (range from 43 to 94)
- Gender (7 males, 7 females)
- Ethnicity
  - Caucasian, African-American, Asian
- Geography
  - Florida, New York, New Jersey, Washington, D.C., Connecticut
- Organ system



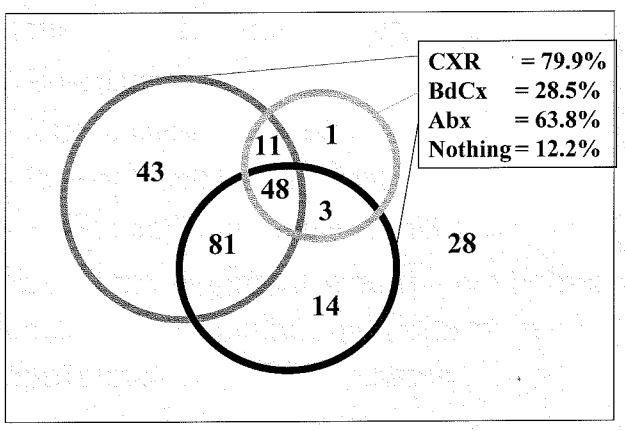
What does Inhalation Anthrax look like to Family Physicians?



Temte & Zinkle, submitted

Diagnostic Modalities Used in Non-hospitalized Patients

(n = 229 of 547 cases)



Family Practice Bioterrorism Study

Summary of Results

- 35 diagnostic categories
- top seven diagnostic categories accounted for 86.1% of anthrax diagnoses
  - pneumonia- 42%
  - influenza- 10%
  - viral syndrome- 9%
  - sepsis- 8%
  - bronchitis-7%

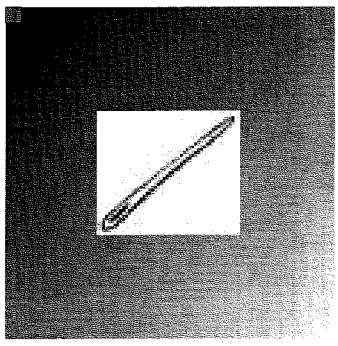
Family Practice Bioterrorism Study

Needle Experts

(technical information)

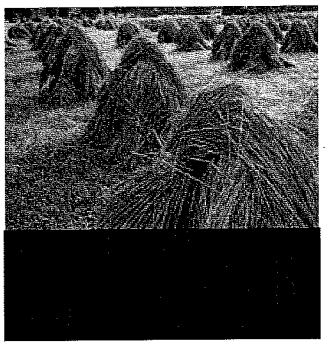
- Most experts in bioterrorism detection and response have come from the military and medical subspecialties
- provide excellent and timely information on technology, identification and treatment
- but, little experience with unfiltered populations

Academic Medical Centers deal with 0.1% of population



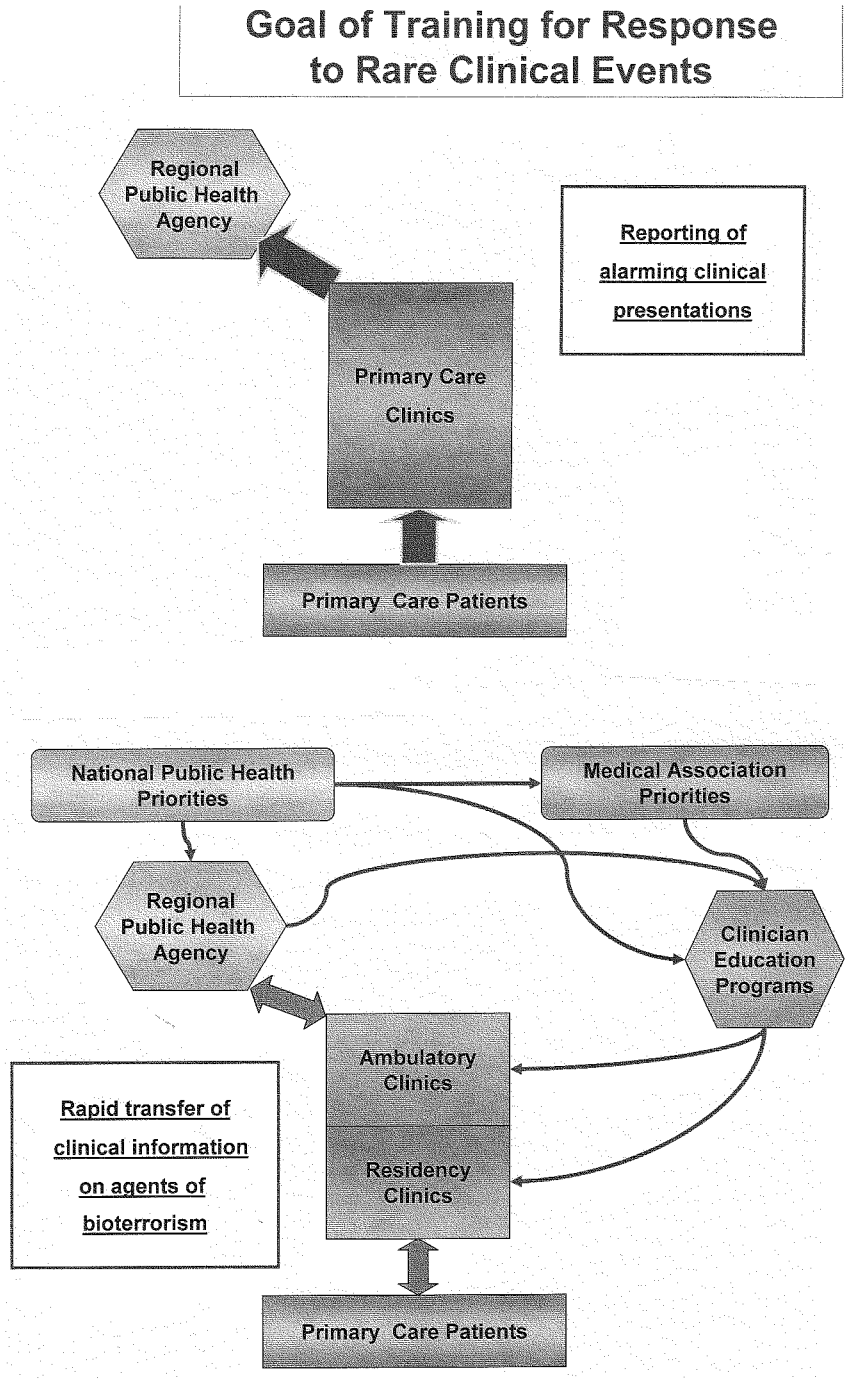
Haystack Experts

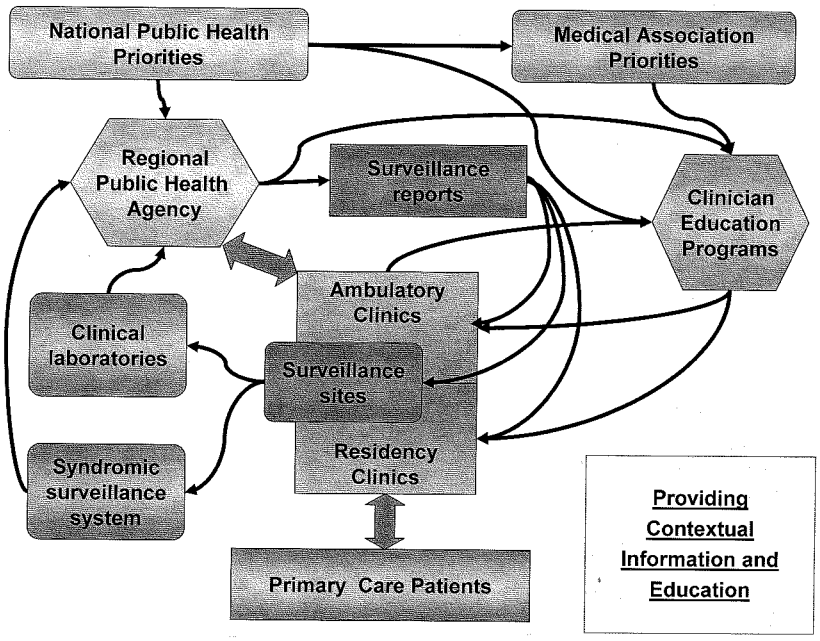
(contextual information)



Primary care physicians see 1/3 of people who consider seeking care for health related concerns

- Very few generalist have been at the BT table
- as of September 17, 2003
  - 2851 MEDLINE-listed articles on bioterrorism had been published
  - only 32 articles mentioned primary or family practice practice as a key word or in the abstract
- but, expansive experience with unfiltered populations, separating wheat from chaff
- routinely address patient psychosocial issues


Goal of Training for Response to Rare Clinical Events
Regional Public Health Agency
Reporting of alarming clinical presentations
Primary Care Clinics
Primary Care Patients
National Public Health Priorities
Medical Association Priorities
Regional Public Health Agency
Clinician Education Programs
Ambulatory Clinics
Residency Clinics
Rapid transfer of clinical information on agents of bioterrorism
Primary Care Patients



final thought...

If you think that there may be a needle in a haystack, and you don't want to miss it, it is essential to know which haystack and what the needle looks like

PREPARED STATEMENT OF CHRISTOPHER K. LAKE, DIRECTOR, HOSPITAL PREPAREDNESS, NEVADA HOSPITAL ASSOCIATION

Thank you, Mr. Chairman for holding this important hearing today on bioterrorism preparedness efforts, and for giving the Nevada Hospital Association the opportunity to be heard. For our nation's hospitals, preparing for an outbreak, whether from a bioterror event or from an emerging disease such as SARs is of paramount importance.

The Nevada Hospital Association is one of the nation's National Bioterrorism Hospital Preparedness Program administrators. As such we work collaboratively with all hospitals, city, county and state governmental units and emergency response organizations within Nevada and in neighboring jurisdictions. We are responsible for evaluating the needs of hospitals and health systems and for the implementation of new technologies and equipment providing early identification of potential terrorist events as well as to protect our nurses, doctors and other biological terror first response personnel.

In April of last year, we conducted a comprehensive hospital assessment and analysis that identifies the strengths, weaknesses, opportunities and threats to our healthcare system as related specifically to bioterrorism preparedness. Disease and syndromic surveillance as well as various technology implementation projects were found to be an area where some opportunities exist.

The assessment documented that more then half of the hospitals conduct syndromic surveillance activities and have policies in place for practitioners to notify appropriate infection control professionals as well as public health officials when needed. The most common syndromes that are monitored at regular intervals include: influenza-like illnesses, rashes with fever, gastroenteritis, sepsis and septic shock, unexplained deaths, and undifferentiated pneumonias. It is believed that these types of patient presentations at our hospital's emergency departments (EDs) will be recognized first by an astute nurse or physician and they will in most cases alert the appropriate personnel that closer study and evaluation may be warranted.

It is difficult to automate real time disease and syndrome surveillance activities for a number of reasons. One of the primary reasons that automation remains complicated is the possibility that the initial number of patients that present at EDs will be low as the outbreak starts to take off and thus may not trigger any alarms that are programmed based on statistically significant variations in patient populations or complaint type. When the numbers become high enough to trigger an alarm, the outbreak would be large enough for physicians to easily identify without the use of the new technology.

Recognizing these hurdles, the Nevada Hospital Association has begun implementing a multi—Prong solution. The first prong is to continually reinforce to all healthcare providers, if you see unusual clinical presentations or unusually high numbers of the same medical complaint think outbreak and alert the appropriate infection control personnel. Our second priority is to standardize the syndromes and patient presentations that hospitals continually monitor so that all hospitals are watching for the same group of diseases affording us the ability to identify possibly subtle or smaller clusters of patients located within a single metropolitan service area. The third prong in our approach will involve the use of technology and the real time collection of ED data.

Nevada EDs are all receiving internet based communications tools that will allow each facility the ability to monitor the current status of all hospitals within our state. This program will provide a magnitude of benefits to help coordinate any healthcare response to terrorism including: the ability for hospitals to send alerts to each other or to groups of provides requesting help, equipment or supplies with the click of a button; the ability to monitor surge capacity within the system and; the ability to monitor system- wide critical inventories just to highlight a few.

We are also working with our vendor to develop a biosurveillance module that will collect real time data regarding the types of patients that are being seen in the hospitals. This device will give doctors and nurses an easy to use, non-laborious and quick tool in which to send data to public health agencies and track identified potential bioweapon syndromes and clinical presentations. The concept of operations is simple. Each hospital's communication screen will have a series of touch buttons that represent the clinical syndromes to be watched. If a physician or nurse sees a patient that presents with one of these syndromes they will simply touch the screen. The computer will track how many individuals at that particular hospital as well as within the State are seeing those types of patients within the last 24 hours.

Local public health departments and state officials will also have the ability to see and monitor all of the syndromes and or each hospital individually or in user defined groups. Each agency will be able to set alarms if defined thresholds are reached and will also have the ability to run reports, query the database and or export the data into other health department computer programs.

We believe this approach will provide the type of information that epidemiologist require to begin an investigation. The collection method will be fast, simple and non-time consuming freeing up the doctors and nurses to be with the patient and not in front of the computer. Lastly and perhaps most importantly the system keeps the clinical interpretation of potential syndromes with the practitioners and does not shift them to a computer routine that could not functionally be programmed with all of the possible medical scenarios.

In conclusion, disease surveillance is a tool which lends itself to the use of technology. However, as with most elements of medicine the hospitals and individual practitioners remain the first line of defense and the primary identifiers of suspected syndromes. Balancing of priorities is critical to ensure that any desire to fund new or unproven surveillance technology will not compete with the fundamental need to adequately protect and equip our hospitals, nurses and doctors to respond and treat the patients that will be inevitable during any terrorist attack or emerging contagious disease. Thank you Mr. Chairman.