Assessing Core Capacity for Infectious Diseases Surveillance

Office of the Assistant Secretary for Planning and Evaluation

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Final Report

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EXECUTIVE SUMMARY

The Office of the Assistant Secretary for Planning and Evaluation in consultation with the CDC contracted with The Lewin Group to develop an investment plan to improve the nation's core capacity for infectious diseases surveillance in light of recent challenges. These challenges include the changing nature of biological threats—including bioterrorism and emerging infections—the rapid pace of technological development, and changes in the health care delivery system.

Dramatic medical successes in the prevention and treatment of infectious diseases led some experts in the 1960s and '70s to proclaim that infections had been conquered in this country and were no longer a significant hazard. Now as we move into the twenty-first century there is renewed anxiety about infectious diseases as biological, sociological, technological, and political factors have converged to promote the emergence of new infections, the resurgence of some conditions that were thought to have been conquered only a few decades ago, and the potential for bioterrorism.

Globalization of the world economy has increased the reach of pathogens. Rapid air travel allows a person who has early, minor, or misleading symptoms of a dangerous, highly contagious infection to expose hundreds of others in planes, in airports around the world, and in every hotel visited or bus ridden. Businesses that transcend political boundaries and rapid transportation allow a food to be contaminated in one country, to further contaminate large quantities of other food in bulk processing plants in another country, and be shipped to yet additional countries where illness results.

Bioterrorism is an increasing concern. Large quantities of highly communicable microorganisms can be grown inexpensively, transported inconspicuously, and released anonymously by terrorists to produce widespread panic, illness, and death.

Other infectious disease challenges are more subtle but represent an equal if not greater threat to the health of the public. Decades of use — and misuse — of antimicrobial agents are inducing antibiotic resistance in organisms once readily treated. Americans are living longer, but their increased longevity is accompanied by increased susceptibility to infectious diseases because other chronic diseases, artificial implants, and the effects of certain medications render them susceptible to infection.

At the same time infectious disease threats are emerging and re-emerging, new technologies are expanding the potential for disease detection, epidemiological analysis, and communication. Various new technologies including pulsed field gel electrophoresis and sequence-based molecular epidemiology allow precise characterization of pathogens to assist epidemiologists in rapidly identifying the sources and patterns of the spread of disease allowing, for example, outbreaks of foodborne illness to be identified and halted within days of the first case report. New information technology offers the potential for real time data collection via the internet and through linkages to electronic patient records, automated analysis, and new options for dissemination. Pattern recognition software can allow the automated detection of unusual

patterns of disease. These technologies offer the potential for surveillance systems to be less dependent on the case report to trigger a public health intervention.

Changes in the health care delivery system pose both an opportunity and a threat to surveillance of infectious diseases. Over the past two decades the population of the United States has rapidly moved into managed care. The promised focus of managed care—managing the health of a population—should bring the goals of the delivery system closer to those of public health. There is great potential for productive collaboration using managed care databases that integrate patient data across the continuum of care.

On the other hand, pressures to reduce lab and other costs have contributed to a narrowing of the range of tests conducted on specimens and the regionalization of private labs. Guidelines encourage physicians to determine treatment based on empirical rather than laboratory findings. New technologies allow private labs to identify the nature of an individual patient's illness faster and cheaper so that growth and identification of the specific pathogen are sometimes unnecessary to recommend appropriate treatment.

Current capacity for infectious diseases surveillance is a product of a century of piecemeal investments as the country has organized to respond to various biological threats. Much of the investment has been categorical, resulting in uneven capacity depending on disease type and fragmentation of surveillance efforts across the spectrum of infectious disease threats. The CDC alone has literally hundreds of data collection systems and data sets.

Legal authority for surveillance rests with the states and localities, adding another dimension to the fragmentation noted above, i.e. not only is surveillance fragmented by disease type, it is also fragmented geographically. The presence of hundreds of jurisdictions makes it difficult and confusing for those required to report infectious diseases and can make it difficult to identify and respond to threats that cross county and state boundaries. The lack of standards for data collection, storage, and transmission makes it hard for states and localities to work collaboratively to develop more effective interfaces with the private sector.

Differing authority and oversight also mean different levels of resources devoted to surveillance at both the state and local level. There is currently a lack of consensus or guidelines for what should be monitored by whom in which populations. As such, capabilities vary substantially both within and across states. Despite expanding expectations for the scope and nature of surveillance efforts, resources devoted to surveillance have changed little at the local level and in many places have actually declined.

Policy-makers and infectious diseases professionals have long recognized the need for change, but no consensus has been developed on the priorities for investment. Hence the Assistant Secretary for Planning and Evaluation commissioned this study to assess where gaps exist in our core capacity for infectious diseases surveillance and recommend an investment framework for improvement.

This investment plan is based on an analysis of recent literature, interviews with over 50 experts in the field, and validation through direct observation of the capacity currently in place for

surveillance in three locations across the country. We worked with a panel of experts to prioritize areas for improvement and refine the investment plan. This panel was drawn from state and local health departments, academia, private health systems, laboratories, and the CDC. This plan addresses the most critical gaps in the national capacity for infectious diseases surveillance as perceived by experts at the time of our study in 1999. It does not reflect investments that have been made to improve surveillance in 2000 or investments planned for 2001.

The plan includes investments that will improve the current system. It also includes investments that will move toward a new system for surveillance which is more integrated and which more heavily leverages the technological advances that have been made in systems to collect, analyze, and disseminate data and information. In some areas the path to improvement is somewhat clear; it only involves an infusion of resources to make headway. In other areas the investments involve demonstration or prototype efforts to experiment with ways to address key gaps. These types of efforts address problems for which solutions have not yet been developed. In some areas we recommend additional studies or panels to better define a problem, develop standards, or to involve key constituencies in proposing solutions to a particularly thorny or technically challenging issue.

Funding to support this investment plan could come from a variety of sources including the federal government, states, localities, and the private sector. Funding could be new or could come from reallocating dollars among activities. This document outlines a five-year investment strategy, but funding for many of the recommended actions will need to continue beyond the time period of this plan. ***Sustained investment will be required to maintain the gains in core capacity made as a result of this plan.***

We want to emphasize the importance of an overarching structure within DHHS to manage this investment plan and to ensure these investments are coordinated with other efforts related to the surveillance infrastructure. These include activities within CDC and other parts of DHHS, individual states and localities, and other parts of the federal government such as the Departments of Defense and Justice. For example, it is critical that technology developed under this investment plan adheres to national standards for data collection, management, transmittal, and analysis currently under development by the CDC. Further, surveillance priorities need to be represented as the nation deals with the larger health system issues of data privacy, security, and confidentiality.

This overarching structure will manage additional research, coordinate investments within this plan and across the full range of investments in the surveillance system, and oversee the various committees and advisory groups that are recommended below. This structure will also oversee the evaluation of all of the initiatives undertaken through this investment plan. Evaluation is critical to ensure that money is well spent and to identify successful practices in demonstration or prototype programs that should be replicated on a national scale.

Overview of Surveillance for Infectious Diseases

Drawing on the literature and the experience of the expert panelists, we identified eight goals for infectious diseases surveillance. These include:

- Detecting outbreaks of infectious disease;
- Detecting changes in the epidemiology of infection;
- Providing information to guide and motivate public health response at both the individual and population level;
- Assessing the health status of the public;
- Evaluating prevention and control interventions;
- Aiding in understanding the etiology and natural history of disease;
- Assisting in health planning;
- Identifying research needs.

Meeting these multi-faceted goals requires collecting data, translating that data into information to support decision-making, and communicating that information to those who need to take action or be informed. The core system for surveillance in this country involves a cascade of activities with each step triggering a response from the next level of the system. Effective surveillance within the current hierarchical system requires a complex set of interactions and information flows among the clinical delivery system, public and private laboratories, and public health personnel at each level of government.

Laboratories and clinical delivery sites identify and report cases of infectious disease to the appropriate public health authorities. Public health officials translate this data into information to guide decision-making with respect to their role in protecting the public against infectious disease threats. These data are first used to guide immediate public health response to individual reported cases of disease to 1) ensure correct diagnosis and treatment, 2) gather more detailed surveillance information such as risk factors, 3) identify, screen, and/or treat contacts who may also be at risk, and 4) to determine the appropriate public health response (e.g., pulling contaminated food off the shelf). These officials then provide data up the chain: local health departments provide data to state health departments who in turn provide data to the CDC. Each subsequent level of government conducts further analyses to understand the nature of biological threats and to develop strategies to address them. The information produced at each level in the system then ideally flows back down the chain to each of the entities involved in surveillance.

This core system is supported by educational institutions that train clinical and public health professionals, accrediting and licensing bodies that set standards, a public and private research establishment that provides supporting technologies, and policy-makers who provide the funding and legal framework for surveillance of infectious diseases.

Our analysis assessed this system for surveillance of infectious diseases. We looked at ways to improve surveillance within the current hierarchical system as well as ways to reorganize the system to better position it to take advantage of advances in communications technology and to

respond to infectious disease threats that increasingly cross county and state boundaries. Military surveillance systems and the United States' participation in global surveillance activities were beyond the scope of this project.

Gaps in the Core Capacity for Infectious Diseases Surveillance

Our analysis identified three types of gaps in the "system" for the domestic surveillance of infectious diseases:

Gaps in the core capacity of the key entities involved in conducting surveillance of infectious diseases. This type of gap refers to the resources within state and local health departments, the CDC, public and private laboratories, and provider systems that allow each entity to perform its role in meeting the goals of surveillance. Our study identified the following specific gaps:

- No clear set of standards exist that defines the critical surveillance needs and associated capacity requirements at all levels of the system.

- Local capacity is not sufficient to ensure adequate performance across key goals of surveillance. Staffing, skill levels, technological capability, and training are uneven across the country leaving some populations less well protected from infectious disease threats than others. Local level public health officials need support from state health departments and the CDC to develop needed skills, to back-up local level staff during outbreaks, for technological support, and to provide guidelines for how to handle various situations.

- Staff capacity at the state and large local level[1] is frequently not adequate to support ongoing analysis of surveillance data to detect changes in the epidemiology of infection, to evaluate surveillance efforts, to plan interventions, and to set priorities.

- Computerized decision and analytic support tools have not been developed to their potential to support infectious diseases surveillance activities.

- The public and private laboratory capacity supporting surveillance has eroded. Public health laboratories often lag behind the private sector in terms of technology—new technologies exist that are not available within public health labs and limited investment is being made to develop new technologies to support public health needs. Meanwhile, private laboratories, which focus on clinical rather than broader public health needs, face cost pressures that have encouraged fewer and less specific tests. Private laboratory consolidation into large regional or national facilities has made the current practice of reporting separately to each jurisdiction cumbersome and impractical.

Gaps in the flow of data and information among the entities involved in surveillance of infectious diseases. Surveillance of infectious diseases involves a series of data and information

[1] Large local refers to cities and metropolitan areas.

flows among the numerous entities involved in surveillance. Our analysis identified a number of critical gaps in these flows:

- Provider and laboratory reporting of infectious diseases is incomplete and not timely. Surveillance systems are too dependent on the case report to trigger a public health response. There is a lack of system infrastructure to facilitate reporting from health care venues to public health.

- A great deal of data flows through the system but feedback and analysis need to be more effectively packaged and disseminated from the CDC to state and local public health officials, from state to local public health officials, and from public health venues to the clinical delivery system. Better feedback would help to engage the delivery system in infectious diseases surveillance. The public health sector has not adequately communicated the importance of surveillance activities to the delivery system.

Gaps in the structures that support surveillance. The core system is supported by educational institutions, accrediting and licensing agencies, the public and private research establishment, and policy-makers. Gaps identified with respect to these supporting structures include:

- Public health workers specifically trained to do infectious diseases surveillance are perceived to be in short supply.

- Training programs do not adequately educate clinical health professionals on their critical role in surveillance.

- Research and development of new laboratory technology is focused on clinical rather than public health applications. Advanced laboratory technology that is available to support surveillance needs to be disseminated and adopted more rapidly.

- Public health misses opportunities to communicate the importance of surveillance to policy-makers and the media. A better understanding of surveillance among these constituencies would help promote adequate funding and a rational legal framework to support it.

In addition to these specific gaps in the system, we identified a number of cross-cutting issues that need to be addressed. These include:

Information technology. Information technology offers opportunity for improvement across many areas, but significant obstacles exist to its widespread deployment. Support is lacking for existing technologies and current capabilities are uneven across states, localities, and disease areas. Lack of data standards and issues of privacy, confidentiality, and security must be resolved before systemic solutions can be implemented.

Widespread innovation but limited sharing. States, localities, and disease areas within CDC are developing multiple solutions to the same problems around data capture, analysis, and transmission. There is a missed opportunity to share information and capture and disseminate lessons learned.

Categorical funding. The historic patterns of categorical funding have impeded the development of a basic surveillance infrastructure capable of meeting the most critical disease threats. The surveillance infrastructure is fragmented and focused on specific diseases rather than on the broad range of threats that face a given population. This has led to data systems that are incompatible and uneven capacity across disease areas. The flexibility of federal funding for emerging infections and bioterrorism has been widely praised for its contribution to core capacity, but critical gaps still remain.

Threats to the Health of the Public

The gaps identified above potentially leave the health of the public susceptible to a wide array of threats. We asked the experts to identify their top concerns—those situations they think the current categorical system is least prepared to respond to. The top four responses were:

- Emerging infections
- Antimicrobial resistance
- Bioterrorism
- Pandemic influenza

Investment Priorities

We recommend a three pronged approach to improving our nation's core capacity for infectious diseases surveillance.

1. ***Improve State and Local Preparedness to Identify and Respond to Infectious Disease Threats.***

2. ***Engage the Health Care Delivery System and the Public as Partners in Infectious Diseases Surveillance.***

3. ***Enhance Public and Private Laboratory Support for Infectious Diseases Surveillance.***

This strategy will address building the necessary infrastructure within state and local governments to ensure that public health departments have adequate resources—both staff and technology—and skill levels to meet the goals of surveillance. This strategy also addresses the critical interface between the public and the private sector and the need to better integrate the medical and public health systems. Much of the information required to do surveillance comes from our nation's clinical delivery system. This system is in the middle of an information technology revolution which offers the potential to radically change how information of public health import is collected and transmitted. Public health must be at the table as standards are created and systems are developed.

Within each area we outline a series of specific investments. Based on the judgment of the panel of experts, we have assigned a priority level to each specific investment.

Level 1: Address immediately

Level 2: Address within two years

Level 3: Address within five years

Investment dollars should be used to fund an oversight structure to manage these investments, evaluate and disseminate results, and coordinate these investments with other surveillance related activities. While the investment plan is presented on a five-year timeline, funding for many of the initiatives needs to be ongoing. Below we present the major objective of each priority and a summary of the specific investments in each priority area.

1. Improve State and Local Preparedness to Identify and Respond to Infectious Disease Threats.

Level 1 Investments

- Increase staffing and skill levels at the local level through a five year grant/technical assistance program that would:
  - Fund state/local partnerships to create performance standards and specify capacity requirements for infectious diseases surveillance at the state/local level and assess performance relative to these standards. This effort would be supported by a national steering committee including representatives from CDC and key professional organizations.
  - Fund partnerships' capacity to meet these standards through training and skill development, increased staffing, and adoption of new technologies.
  - Create federal, state, and regional support structures to assist localities in meeting performance standards including back-up staff, guidelines, technical support, and training.

Level 2 Investments

- Fund the expansion of epidemiology staff capacity that crosses disease areas in states, large cities, and regional partnerships.
- Fund the dissemination of existing or the development of new prototype analytic and decision support tools to support surveillance activities through grants to health departments or partnerships between health departments and software developers, academic institutions, or other private entities. Examples might include refining methodologies for conducting surveillance, applications of data mining, pattern recognition, and geographic information system technologies.

Level 3 Investments

- Encourage students to pursue careers in epidemiology and infectious diseases surveillance by providing scholarships and funding field placements for trainees and faculty of public health schools.

- Fund the development of model infectious diseases surveillance oriented curricula for epidemiologists in schools of public health.

2. Engage the Health Care Delivery System and the Public as Partners in Infectious Diseases Surveillance.

Level 1 Investments

- Fund demonstration projects with the goal of creating and deploying efficient, easy-to-use, and rapid automated reporting systems nationwide based on national standards.

- Fund the development of new tools to enhance two-way communication between the public health and provider communities. Emphasize projects that document ways in which surveillance activities add value and improve health.

Level 2 Investments

- Fund infection control professionals in a sample of sentinel health care facilities to perform an expanded role in infectious diseases surveillance.

Level 3 Investments

- Fund CDC to make surveillance activities a standard of practice among providers by awarding grants to develop model surveillance curricula and incorporate it into educational programs for clinical health professionals. Promote licensing agencies and certification boards to require a basic knowledge level regarding the role of providers in surveillance.

- Award grants to develop and disseminate training materials and educational programs to improve the ability of state and local health officials to engage communities in infectious diseases surveillance and to communicate infectious diseases surveillance and control priorities to policy-makers and media leaders. Seek private foundation funding for this grant program.

- Fund the development and distribution of newsletters (paper and/or internet-based) that can be tailored by state and local health departments to provide ongoing education to key constituent groups.

3. Enhance Public and Private Laboratory Support for Infectious Diseases Surveillance.

Level 1 Investments

- Create a multi-disciplinary, public-private advisory panel to clarify the needs and roles of public and private laboratories in supporting infectious diseases surveillance, to develop rational and fair incentives to private laboratories to provide information and specimens for surveillance, and to monitor the changing utility of laboratory data in supporting infectious diseases surveillance.

- Fund a prototype project to standardize laboratory reporting requirements across selected jurisdictions, centralize reporting venues, and implement electronic laboratory reporting. If successful, expand rapidly to other areas.

Level 2 Investments

- Create a national laboratory technology assessment committee to: assess current gaps in the laboratory technology supporting infectious diseases surveillance and recommend approaches for closing those gaps; identify, assess, and recommend deployment strategies for new or existing laboratory technologies; and allocate a pool of money that would be targeted at "raising the bar" for public health laboratory technological capabilities.

- Create a grant program administered by CDC (or CDC in partnership with NIH) with the advice of the national laboratory technology assessment committee (above) to award extramural grants to develop new laboratory technologies to support the surveillance of infectious diseases.

- Fund intramural research at CDC aimed at improving the laboratory technology supporting infectious diseases surveillance.

Overarching Management and Evaluation Structure

Level 1 Investment

- Fund an overarching structure to manage and evaluate these investments, scan the environment for innovative surveillance related activities, disseminate information on these activities, and coordinate this plan with other infectious diseases surveillance initiatives. This structure should include an advisory committee composed of representatives from CDC, state, and local health departments, public and private laboratories, the provider community, and other key stakeholder groups.

Conclusion

Even though the gaps addressed in this investment plan were mostly identified through interviews and site visits with individuals and venues outside of the federal government, not surprisingly the gaps appear to be fairly consistent with gaps as perceived by key decision-makers in the federal government; therefore our proposals have some degree of overlap with current federal priorities. Implementation of this investment plan, however, would require a substantial increase in funding relative to current levels. Increases would include federal investment in human capital to support surveillance at the state and local level through efforts focused on staffing levels, training and skill development, technological support, provider and public education, role definition, etc. These efforts would be funded along side current efforts to increase technological capacity. Technology has tremendous potential to improve infectious diseases surveillance and free up existing staff resources to analyze data, investigate outbreaks, and implement prevention measures. However, many localities lack people to perform even the most basic functions. Additionally, technological improvements to surveillance capacity will require targeted investments to ensure that staff capacity, training, and technical support are in place to allow new systems to operate effectively and change the way surveillance is conducted in this country.

The overlap of this plan with existing activities and priorities points to the importance of the oversight and evaluation component of this investment plan. Oversight and coordination of the full range of surveillance related activities is critical to ensure that money is used wisely. These efforts must ensure that the system becomes less rather than more fragmented over time and must support a movement from the paradigm of medical care and public health as completely separate toward one that considers them as parts of an integrated whole. Evaluation efforts will be critical to objectively assess the ability of various approaches to have a measurable impact on the performance of our national "system" for infectious diseases surveillance.

This investment plan should be evaluated in terms of its success in:

- Improving local preparedness to identify, assess, and respond to infectious disease threats.
- Engaging the clinical delivery system, laboratories, and communities as partners in protecting the health of the public against infectious disease threats.
- Improving analytic capacity to detect outbreaks and changes in the epidemiology of infection and plan and evaluate prevention and control strategies.
- Streamlining and simplifying the current "systems" for infectious diseases surveillance.
- Ensuring the technology (laboratory and information technology) supporting infectious diseases surveillance is on the cutting edge.

INTRODUCTION

The Office of the Assistant Secretary for Planning and Evaluation in consultation with the CDC contracted with The Lewin Group to develop an investment plan to improve the nation's core capacity for infectious diseases surveillance in light of recent challenges. These challenges include the changing nature of biological threats—including bioterrorism and emerging infections—globalization, the rapid pace of technological development, and changes in the health care delivery system.

Dramatic medical successes in the prevention and treatment of infectious diseases led some experts in the 1960s and '70s to proclaim that infections had been conquered in this country and were no longer a significant hazard. Now as we move into the twenty-first century there is renewed anxiety about infectious diseases as biological, sociological, technological, and political factors have converged to promote the emergence of new infections, the resurgence of some conditions that were thought to have been conquered only a few decades ago, and the potential for bioterrorism.

Globalization of the world economy has increased the reach of pathogens. Rapid air travel allows a person who has early, minor, or misleading symptoms of a dangerous, highly contagious infection to expose hundreds of others in planes, in airports around the world, and in every hotel visited or bus ridden. Businesses that transcend political boundaries and rapid transportation allow a food to be contaminated in one country, to further contaminate large quantities of other food in bulk processing plants in another country, and be shipped to yet additional countries where illness results.

Bioterrorism is an increasing concern. Large quantities of highly communicable microorganisms can be grown inexpensively, transported inconspicuously, and released anonymously by terrorists to produce widespread panic, illness, and death.

Other infectious disease challenges are more subtle but represent an equal if not greater threat to the health of the public. Decades of use — and misuse — of antimicrobial agents are inducing antibiotic resistance in organisms once readily treated. Americans are living longer, but their increased longevity is accompanied by increased susceptibility to infectious diseases because other chronic diseases, artificial implants, and the effects of certain medications render them susceptible to infection. It is paradoxical that the extraordinary successes of infectious disease prevention and control may themselves increase the hazards from those same conditions; most physicians have limited clinical experience with many significant infectious disease threats, and a large portion of the public have been protected from epidemic and endemic infections that were part of the day-to-day reality for their parents and grandparents. As a result, the public's responses to infectious disease threats are muted.

At the same time that infectious disease threats are emerging and re-emerging, new technologies are expanding the potential for disease detection, epidemiological analysis, and communication. Various new technologies including pulsed field gel electrophoresis and sequence-based molecular epidemiology allow precise characterization of pathogens to assist epidemiologists in rapidly identifying the sources and patterns of the spread of disease allowing, for example,

outbreaks of foodborne illness to be identified and halted within days of the first case report. New information technology offers the potential for real time data collection via the internet and through linkages to electronic patient records, automated analysis, and new options for dissemination. Pattern recognition software can allow the automated detection of unusual patterns of disease. These technologies offer the potential for surveillance systems to be less dependent on the case report to trigger a public health response.

Changes in the systems to provide and pay for health care pose both an opportunity and a threat to surveillance of infectious diseases. Concerns over double digit health care inflation in the eighties made cost control a number one priority for both policy-makers and the major payers for health care delivery, private employers. Over the past two decades the population of the United States has rapidly moved into managed care. The promised focus of managed care—managing the health of a population—should bring the goals of the delivery system closer to those of public health. There is great potential for productive collaboration in prevention of illness and in using managed care databases to integrate patient data across the continuum of care.

On the other hand, concerns about costs have changed clinical and laboratory practices in ways that limit the availability and reduce the utility of information upon which infectious disease surveillance has traditionally been based. Clinical studies have shown that it is often not necessary to obtain microbial cultures to treat many conditions effectively, such as diarrhea, urinary tract infection, and even pneumonia. In these settings, a clinician can prescribe treatments — often broad-spectrum antibiotics — and achieve cure rates equal to those treatments guided by culture results, and the cures are less costly. These new approaches to clinical practice have been rapidly adopted by managed care organizations, and they have been generally accepted by the practicing community.

The need to be cost-effective also drives laboratory practices. Intense competition and razor-thin profit margins among laboratories have driven the adoption of highly efficient processes that narrow the range of tests conducted on specimens. New technologies allow private labs to identify the nature of an individual patient's illness faster and cheaper so that growth and identification of the specific pathogen are sometimes not needed to recommend appropriate treatment. While this represents an advantage to efficiency and effectiveness of care for the individual patient, it obviates the clinical need for tests of public health significance. Competition among laboratories has led to their consolidation into large organizations serving multi-state regions or even the nation as a whole. This has further eroded the practical utility of laboratory data. Those centralized laboratories may have neither the ability, motivation, nor legal obligation to provide notification about reportable diseases to the hundreds of local jurisdictions they serve, but these local jurisdictions remain the points where surveillance and case investigations begin.

Current capacity for infectious diseases surveillance is a product of a century of piecemeal investments as the country has organized to respond to various biological threats. Much of the investment has been categorical, resulting in uneven capacity depending on disease type and fragmentation of surveillance efforts across the spectrum of infectious disease threats. The CDC alone has literally hundreds of data collection systems and data sets.

Legal authority for surveillance rests with the states and localities, adding another dimension to the fragmentation noted above, i.e. not only is surveillance fragmented by disease type, it is also fragmented geographically. The presence of hundreds of jurisdictions makes it difficult and confusing for those required to report infectious diseases and can make it hard to identify and respond to threats that cross county and state boundaries. The lack of standards for data collection, storage, and transmission makes it hard for states and localities to work collaboratively to develop more effective interfaces with the private sector.

Differing authority and oversight also mean different levels of resources devoted to surveillance at both the state and local level. There is currently a lack of consensus or guidelines for what should be monitored by whom in which populations. As such, capabilities vary substantially both within and across states. Despite expanding expectations for the scope and nature of surveillance efforts, resources devoted to surveillance have changed little at the local level and in many places have actually declined.

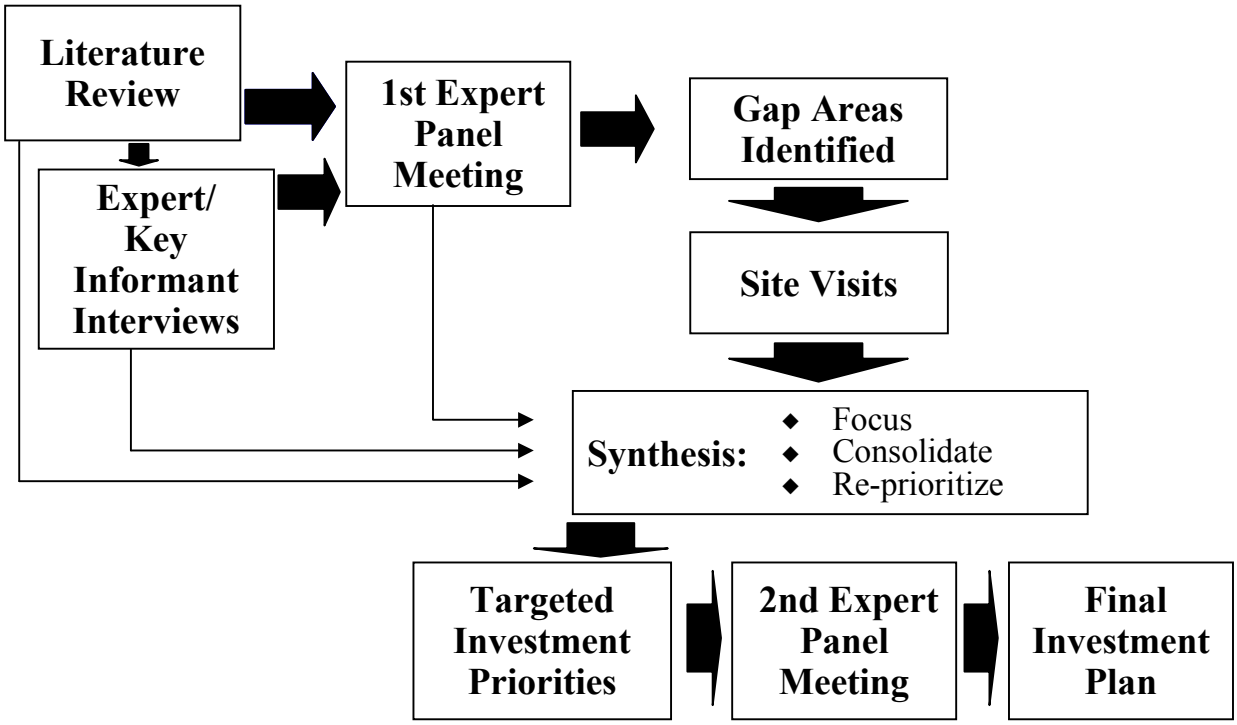
Policy-makers and infectious diseases professionals have long recognized the need for change, but no consensus has been developed on the priorities for investment. Hence the Assistant Secretary for Planning and Evaluation commissioned this study to assess where gaps exist in our core capacity for infectious diseases surveillance and recommend an investment framework for improvement.

METHODOLOGY

This investment plan is based on an analysis of recent literature, interviews with over 50 experts in the field, and validation through direct observation of the capacity currently in place for surveillance in three locations across the country. Additionally, we received input from a panel of experts drawn from state and local health departments, academe, private provider systems, laboratories, and the CDC. The investment plan that follows addresses the most critical gaps in the national capacity for infectious diseases surveillance as perceived by experts. This plan reflects the state of surveillance in 1999. It does not look at programs implemented in 2000 or planned for 2001.

In performing this research, each major project task (i.e., literature review, key informant interviews, site visits, and expert panel meetings) directly informed the substance and approach for each subsequent task. Exhibit 1 depicts the order in which we conducted these activities.

EXHIBIT 1: PROJECT TASKS



Below, we describe the methodology used to conduct each project task.

Literature Review

We thoroughly reviewed the literature pertaining to infectious diseases surveillance. This helped us to synthesize current thinking on the topic and to pinpoint specific issues or gaps within surveillance activities for which there is widespread concern among published authors and researchers. The key issues identified through the literature review formed the basis of our subsequent interviews with key informants.

Our initial search of the literature focused on five key questions:

- What is disease surveillance?
- What are the key characteristics of infectious diseases surveillance systems?
- What are the key characteristics of the current domestic surveillance system?
- How should the performance of a disease surveillance system be evaluated?
- What recent examples of infectious disease outbreaks are relevant to the study objectives?

The Lewin Group developed a search strategy to locate relevant articles that specifically addressed these questions. This strategy targeted peer-reviewed journal articles and other published and unpublished written materials addressing the issues raised by these questions.

We compiled the information and then synthesized the key themes which emerged from the literature review. These themes helped us to construct the interview guides for the key informant interviews discussed below.

Key Informant Interviews

After completing the literature review, we conducted detailed conversations with 55 surveillance experts around the country and in Canada. These surveillance experts included representation from local and state governments, CDC, academic institutions, laboratories, private providers, managed care organizations, the military, and the Veterans Administration. The key informants were chosen based on pooled lists of possible candidates from ASPE, CDC, and The Lewin Group. Key informants were ultimately chosen based on a diversity of characteristics, including current and previous positions, specific areas of expertise, geography, and training. The full list of key informants can be found in Appendix A.

We developed a conversation guide to structure our discussions. The conversation guide was modularized such that each key informant responded to a somewhat different set of questions. The topics covered in the conversation guide flowed from the key issues identified in the literature review, but, the Lewin staff member leading the conversation was at liberty to pursue additional or more detailed avenues of discussion. The complete interview protocol can be found in Appendix B.

As part of this interview we provided each key informant with one of six "surveillance scenarios" and asked each person to describe: How should the infectious diseases surveillance process work in dealing with this scenario? Where would it be likely to breakdown? Where would you invest resources to improve capabilities to handle this scenario? And what would you hope to achieve from this investment?

The six scenarios each covered a different topic, ranging from "routine" surveillance, to food borne illness, to bioterrorism. An example of a scenario is as follows:

> *The challenge is to recognize a serious infection that does not fit the case definitions of any of the major reportable diseases and causes severe debilitation but not death. This infection's source can be contaminated food or water. The incubation period is approximately 2-5 days, and the attack rate is about 30%. Its symptoms include a very unusual and severe headache, severe fatigue, and minor diarrhea. It is very debilitating – people are wiped out for at least a week – but physicians typically do not place patients in the hospital. Few die because of it, and the occasional deaths are due to a variety of complications.*

We also asked the key informants to provide their definition of surveillance; describe surveillance successes and failures in which they were personally involved to illustrate the current strengths and weaknesses of surveillance capacity; discuss the strengths and limitations of

surveillance with regard to selected issues including education and training, staffing, technology, information flow, legal authority, the impact of managed care, and other topics; and identify the types of situations that represent the greatest threat to the population's health.

First Expert Panel Meeting

A blue ribbon expert panel was convened to provide input and guidance in developing the investment plan. Panelists included representatives of state and local health departments, private provider systems, public health laboratories, the CDC, and academic institutions. The key informants who served on the expert panel are identified in Appendix A.

These individuals played an important role on the project, participating in a number of activities, including key informant interviews and two expert panel meetings. Panelists also acted as a general resource for the project, responding to specific questions from project staff on request.

The first expert panel meeting took place on October 5, 1999. The Lewin Group facilitated the meeting. In addition to the expert panelists, Dr. Margaret Hamburg, Assistant Secretary for Planning and Evaluation, Department of Health and Human Services and a number of staff from her office participated.

The three primary goals of the first expert panel meeting were to:

- Identify and prioritize opportunities to improve domestic surveillance of infectious diseases;
- For each opportunity area:
  - To identify minimal performance goals and objectives;
  - To identify what core capacity needs to exist to meet these objectives;
  - To specify the interventions/investments that would be required to attain the core capacities and performance goals.
- Prioritize investments.

Site Visits

Following the first expert panel meeting, we conducted site visits to test the framework for investment developed by the expert panelists against the priorities of surveillance systems that have or are currently undertaking efforts to improve their surveillance capabilities. The site visits were conducted in January and February, 2000. The three locations visited included:

- Oregon,
- West Virginia, and
- Baltimore.

These sites were chosen in order to capture a range of characteristics. For example, Oregon is widely perceived as a "best practice" site. West Virginia has recently implemented a number of model initiatives and is predominantly rural. Baltimore is a large city region and functions independently from the state in which it is located.

Goals of the site visits included:

- Gain an "on the ground" understanding of the existing capacity for infectious diseases surveillance and the obstacles to effective performance.
- Identify and compare the opportunities/gaps, performance standards, and priorities for investment as developed by the expert panel to the those of state and local systems.
- Understand what contributes to achieving "best practice" performance.
- Identify existing models or generate ideas for addressing the opportunities/gaps identified by the expert panelists.

We developed a modularized site visit protocol that was used for each of the three sites. Areas of inquiry included: background on the structure and organization of the site's capacity for surveillance; perceptions of performance relative to goals of surveillance; examples of recent outbreaks and how they were handled; questions on how specific organizational units and the public health laboratories function; and questions for private physicians and laboratories on their interaction with the public health department.

About half of each interview was devoted to testing the results of the expert panel. We asked each respondent questions about two to three opportunity areas depending on their area of expertise. We also asked for their perspectives on the importance of each opportunity area, specific goals and performance standards for achievement, resources required to meet goals, and the practical effects of meeting goals. The protocol can be found in Appendix C.

The site visits, in particular, helped us to identify the most important gap areas as well as provided us with initial information on the magnitude of investments that would be required. Site visit reports can be found in Appendix D.

Synthesis

Following the site visits, we synthesized the information from all of the data collection efforts to produce a consolidated set of six priority investment areas, specific objectives in each area, and an associated investment approach. This plan provided the material for discussion at the second expert panel meeting and the basis for the investment plan presented below.

At this time we also conducted a "goals and performance" exercise with the expert panelists as a check on whether the focus of the investment plan was consistent with what the experts perceived to be gaps in performance relative to critical goals of infectious diseases surveillance. These goals were initially drawn from the literature and then refined by the experts in the first

panel meeting. The exercise asked each panelist to rank the importance of eight goals of surveillance at each level of government on a five point scale. It then asked each panelist to rank system performance relative to each goal at each level of government. The resulting data was arrayed in a matrix format to visually depict gaps in the system. This exercise is attached as Appendix E.

Second Expert Panel Meeting

A second meeting of the expert panel was held on March 1, 2000. The primary goal of this meeting was to formulate the draft investment plan. The panel first discussed the overall investment approach and then spent the bulk of the meeting discussing each of the six gap areas/investment priorities in-depth.

Final Report Preparation

Based on the results of this expert panel meeting, we refined the six priority areas, the investment objectives, and the investment approach, and began drafting this final report. As a final exercise we asked the expert panelists to rank the list of investments. This ranking exercise appears as Appendix F. Drafts of the investment plan were reviewed by representatives of the Office of the Assistant Secretary for Planning and Evaluation at the Department of Health and Human Services, our project liaisons at the Centers for Disease Control and Prevention, and the expert panelists.

FRAMEWORK FOR INFECTIOUS DISEASES SURVEILLANCE

Infectious diseases are the leading cause of death worldwide, and the third leading cause of death in the United States. In the 20th century therapeutic advances in treating infectious diseases, such as the introduction of antibiotics and the development of vaccines have decreased the risks posed by infectious diseases. For several decades, infectious diseases seemed to be partially controlled by such methods, but in the last twenty years, infectious diseases have once again become a threat.

Surveillance is widely regarded as the key to detecting new and emerging diseases, as well as tracking incidence and prevalence of established diseases. Surveillance data help detect unusual disease patterns and trigger control efforts. In 1963, Alexander Langmuir, organizer of the Epidemic Intelligence Service (EIS) at the Centers for Disease Control (CDC), coined the modern definition of public health surveillance, which was later endorsed by the World Health Organization (WHO). Langmuir defined public health surveillance as having three parts:

1. The systematic *collection* of pertinent data,
2. The orderly *consolidation* and *evaluation* of the data, and
3. The prompt *dissemination* of results to those who need to know (i.e., relevant health authorities).

The data referred to in the above definition include information such as the diagnosis of the disease, disease severity, geographic distribution of cases, and the route of transmission. The unit of analysis in surveillance is a case, which is an instance of a single individual with the disease.

The definition implies an ordered sequence of discrete activities or events that can be used both for circumscribing the surveillance process and assessing what needs to be improved. The following example describes the essential steps in the surveillance process as:

- ***Diagnosis of a Health Event*** by clinicians and laboratories.
- ***Reporting of Health Events and Other Disease Information*** to local, state, and/or federal health agencies. Reporting sources include clinicians, laboratories, hospitals, schools, and vital statistics records.
- ***Management of Health Event Data***: Once information is reported, the data is collected, entered into a data management system, and edited. The information is then analyzed to establish baseline disease information and time trends. The data is examined for the identification and documentation of outbreaks. Reports are then generated and disseminated so that appropriate public health actions can be taken.

Surveillance activities can recognize the occurrence of new or emerging infections and track the prevalence of infectious agents already established in human populations. Effective surveillance programs are able to detect unusual clusters of disease, document the geographic and demographic spread of an outbreak, and estimate the magnitude of an infectious disease problem. In addition, effective surveillance helps identify the natural history of a disease and factors responsible for emergence, facilitates laboratory and epidemiological research, and assesses the success of specific intervention efforts. Poor surveillance leads to incomplete, non-representative, and untimely disease reporting. These gaps leave policy-makers and medical personnel without a basis for setting policy to control the spread of infectious disease and to mount an effective prevention and treatment campaign. For example, in the 1980s tuberculosis was no longer considered a significant problem and surveillance of the disease declined. The reemergence of the disease in the early 1990s, particularly multi-drug-resistant strains, took the public health and medical communities by surprise.

Below we discuss gaps in domestic surveillance activities in terms of two complementary frameworks. The first framework reviews the goals of surveillance and explores which goals should be the focus of new investment initiatives. The second framework assesses investment opportunities for improving surveillance in terms of the structure of and relationships among the entities, resources, and environmental factors involved in surveillance.

Goals of Surveillance

Based on a review of relevant literature and the advice of the expert panel, we identified eight goals for infectious diseases surveillance. These include:

- *Detecting outbreaks of infectious disease*. Infectious diseases surveillance allows public health officials to differentiate between endemic and epidemic levels of disease by placing current incidence statistics in the perspective of normal levels. An epidemic, or outbreak, of a disease is its occurrence at an unexpectedly high frequency. Determination of whether the level of disease is higher-than-normal is only possible when the "usual" or baseline rate of the disease is known. Surveillance systems regularly monitor the health status of populations and therefore allow the identification of baseline levels of different diseases. For instance, surveillance efforts have shown that the endemic level of measles in the U.S. is extremely low. Nearly all new outbreaks can be attributed to imported measles cases. This type of information helps policy-makers focus disease control efforts.

- *Detecting changes in the epidemiology of infection.* Patterns of infection change over time. For instance, a disease that at one time primarily affected young children may now have its greatest effect on young adults or the elderly. Many factors can account for changes in the epidemiology of infection, such as implementation of a vaccination campaign or mutations in the infectious agent. For example, after vaccination for measles became routine in the United States, the average age at which individuals became infected rose significantly, changing the healthcare needs of the affected population. Surveillance identifies these important trends.

- *Providing information to prompt and guide a public health response at both the individual and population level*. Without a firm understanding of who, where, and why people become infected and by what, the public health community would have no reasonable approach for tackling a problem caused by an infectious agent. Surveillance was instituted to enable society to deal with immediate communicable disease threats. Surveillance information is critical for making intelligent decisions for protecting the health of the public both at the population and the individual level. Botulism and meningitis surveillance both illustrate the multiple roles of surveillance information. The purposes of reporting suspected botulism are 1) to aid clinicians in making the diagnosis, since this is a rare disease (many state labs are the only sources of botulism testing), 2) providing access to treatment (only available through the public health service with the approval of state health officials), and 3) identifying the source of disease through a public health investigation of the food history, testing foods in the refrigerator, etc. The source could be either a home-canned product, which generates one kind of public health response, or a commercial product which generates a very different response. In the case of meningitis surveillance the primary goal at the local level is to identify close family and child day care contacts for prophylactic administration of rifampin within 48 hours to prevent other cases of disease.

- *Assessing the health status of the public*. A primary role of disease surveillance is the assessment of the overall health status of the public. Infectious diseases surveillance provides descriptive information on the most frequent causes of morbidity and mortality in communities, the magnitude of health problems, and the demographic and geographic distribution of diseases.

- *Evaluating prevention and control interventions*. Prevention guidelines, screening, vaccination, efforts to change lifestyles, and other disease prevention and control interventions are designed to improve health outcomes. Surveillance systems enable the evaluation of these

efforts by charting changes in health status before and after introduction of the intervention. For example, active surveillance of Group B Strep funded through the Emerging Infections Program has monitored the burden of disease over time and been crucial in measuring the uptake and impact of prevention measures. Likewise, the incidence of diseases for which vaccines are available can be used to assess the success of efforts to increase vaccination rates. Using surveillance data to evaluate prevention programs can improve program designs and better target public awareness campaigns.

- *Aiding in understanding the etiology and natural history of disease*. Disease surveillance data can be used to help understand the etiology (factors of causation of disease) and natural history of diseases. Surveillance can provide information that helps to determine the mode of transmission of diseases (e.g., vector-borne, waterborne), short- and long-term trends of disease including the incidence, prevalence, and case fatality over time, risk factors for new and old diseases (e.g., age, gender, co-morbidities), and environmental factors related to diseases (e.g., warm climates, seasonal changes in incidence). However, undertaking surveillance exclusively for research purposes is uncommon since specific aspects of a disease are better investigated by more detailed data collection and tracking of cases (e.g., registries).

- *Assisting in health planning*. Information obtained from surveillance systems can be used to guide health planning. For example, health departments can use surveillance information to help prioritize efforts to combat the most prevalent preventable diseases, set target goals (e.g., Healthy People 2010), and estimate resource needs.

- *Identifying research needs*. Disease surveillance can be used to identify gaps or unexplored areas of research. For example, surveillance data may reveal the emergence of a new antibiotic resistant strain of bacteria such as happened when penicillin resistant strains of gonorrhea emerged and required research to develop new drugs for treatment. Additionally, surveillance may reveal that a certain disease has emerged in a previously unaffected population, indicating the need for studies on possible reasons for this shift (e.g., socio-economic changes, influx of people from other communities).

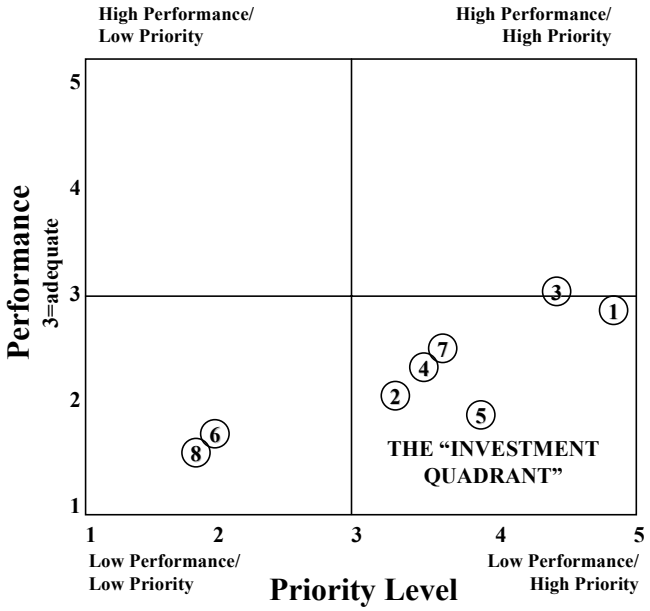
Meeting these goals requires collecting data, translating that data into information to support decision-making, and communicating that information to those who need to take action or be informed. Performance relative to these goals varies widely across jurisdictions. While all of these surveillance goals are important, the prioritization of these goals also differs among various surveillance entities. In developing the plan to improve the core capacity, it was critical to ensure that investments targeted high priority goals for which the current level of performance is inadequate.

Based on the assessment of the expert panelists, a number of goals fall into the "low performance/high priority" category. At the local level, as shown in Exhibit 2, there are five such target goals, including: detecting outbreaks, detecting changes in the epidemiology of infection, assessing the health status of the public, evaluating prevention and control interventions, and assisting in health planning.

EXHIBIT 2: GOALS OF SURVEILLANCE – PERFORMANCE AND PRIORITIES AT THE LOCAL LEVEL

✓1. Detecting outbreaks
✓2. Detecting changes in the epidemiology of infection
3. Providing information to guide public health response
✓4. Assessing the health status of the public
✓5. Evaluating prevention and control interventions
6. Aiding in understanding the etiology and natural history of diseases
✓7. Assisting in health planning
8. Identifying research needs

✓ = investment area

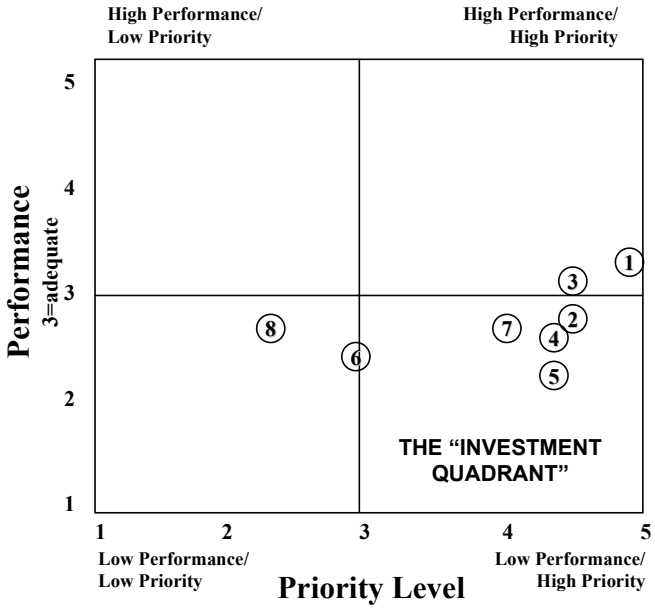


At the state level, as shown in Exhibit 3, the four goals that fall into the "low performance/high priority" category include: detecting changes in the epidemiology of infection, assessing the health status of the public, evaluating prevention and control interventions, and assisting in health planning.

EXHIBIT 3: GOALS OF SURVEILLANCE – PERFORMANCE AND PRIORITIES AT THE STATE LEVEL

1. Detecting outbreaks
✓2. Detecting changes in the epidemiology of infection
3. Providing information to guide a public health response
✓4. Assessing the health status of the public
✓5. Evaluating prevention and control interventions
6. Aiding in understanding the etiology and natural history of diseases
✓7. Assisting in health planning
8. Identifying research needs

✓ = investment area

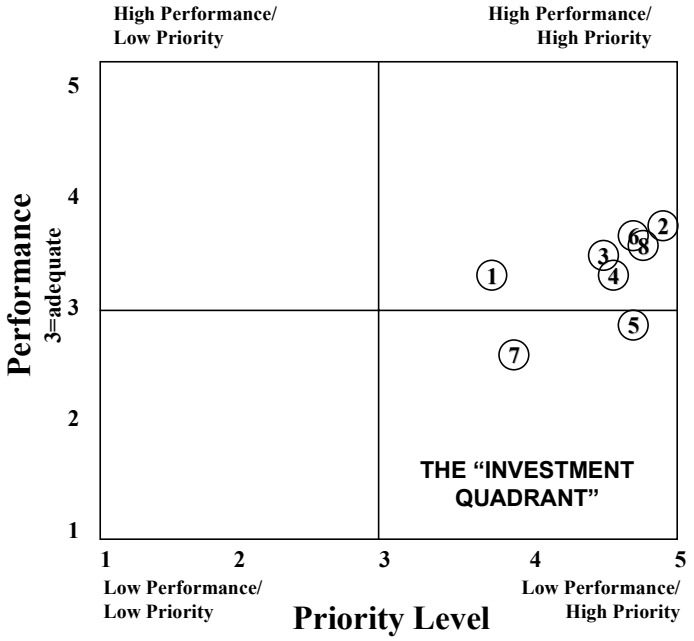


Finally, at the CDC level, as shown in Exhibit 4, only two goals fall into the "low performance/high priority" category: evaluating prevention and control interventions and assisting in health planning.

EXHIBIT 4: GOALS OF SURVEILLANCE – PERFORMANCE AND PRIORITIES AT THE CDC LEVEL

1. Detecting outbreaks
2. Detecting changes in the epidemiology of infection
3. Providing information to guide public health response
4. Assessing the health status of the public
5. ✓ Evaluating prevention and control interventions
6. Aiding in understanding the etiology and natural history of diseases
7. ✓ Assisting in health planning
8. Identifying research needs

✓ = investment area



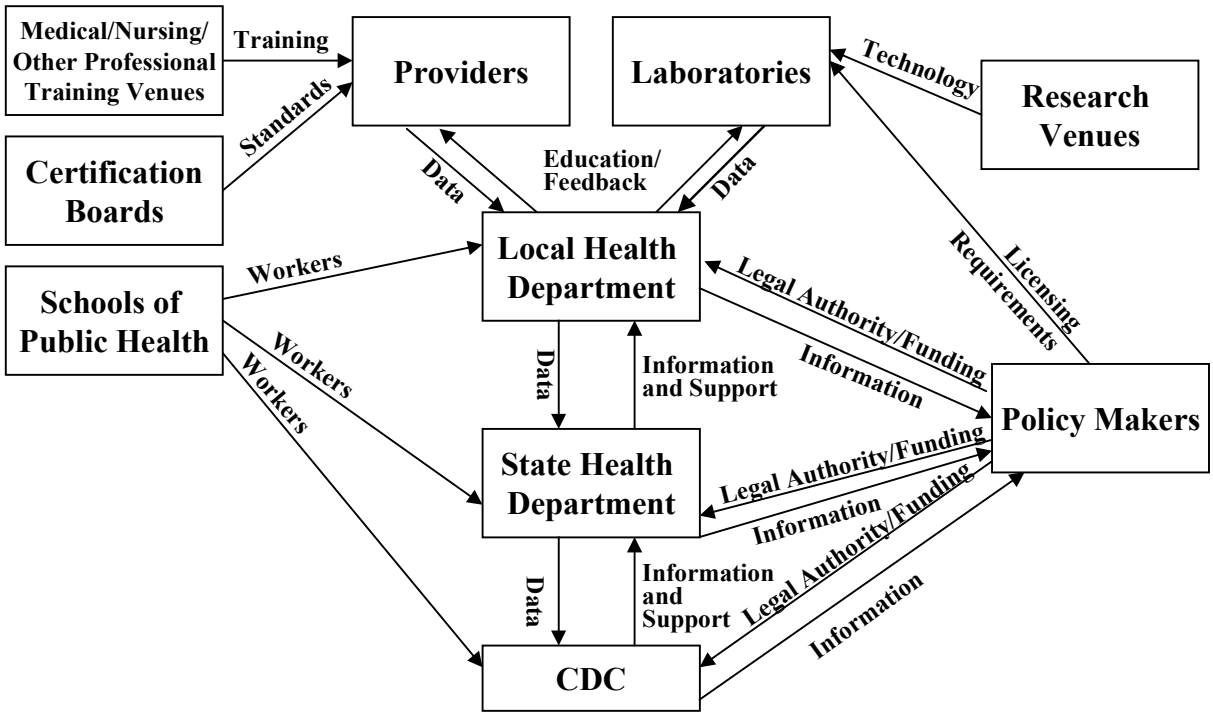
In comparing the categorization of goals across the three levels of surveillance, the local level has the greatest number of target goals, followed by the state level, with the CDC level having the best perceived performance overall. Thus, not only should an effective plan to improve the core capacity for infectious diseases surveillance target specific surveillance goals that fall into the "low performance/high priority" category, but should also focus resources on improving performance at the local level either through direct investment in local capacity or through federal and state support and the development of new data flow arrangements.

KEY GAPS IN THE CORE CAPACITY FOR INFECTIOUS DISEASES SURVEILLANCE

In accomplishing the goals described above, the core system for surveillance in this country involves a cascade of activities with each step triggering a response from the next level of the system. As depicted in Exhibit 5, effective surveillance within the current hierarchical system requires a complex set of interactions and information flows among the clinical delivery system, public and private laboratories, and public health personnel at each level of government. Laboratories and clinical delivery sites identify and report cases of infectious disease to the appropriate public health authorities. These data are used to guide immediate public health response to individual reported cases of disease to 1) ensure correct diagnosis and treatment, 2) gather more detailed surveillance information such as risk factors, 3) identify, screen, and/or treat contacts who may also be at risk, and 4) determine the appropriate public health response (e.g., pulling contaminated food off the shelves). Moreover, public health officials translate this

data into information to guide decision-making with respect to their broader role in protecting the public against infectious disease threats. These officials then provide data up the chain: local health officials provide data to state health officials who in turn provide data to the CDC. Each subsequent level of government conducts further analyses to understand the nature of biological threats and to develop strategies to address them. The information produced at each level in the system then ideally flows back down the chain to each of the entities involved in surveillance.

EXHIBIT 5: INTERACTIONS AND INFORMATION FLOWS FOR INFECTIOUS DISEASES SURVEILLANCE



This core system is supported by educational institutions that train clinical and public health professionals, accrediting and licensing bodies that set standards, a public and private research establishment that provides supporting technologies, and policy-makers who provide the funding and legal framework for surveillance of infectious diseases.

Our analysis assessed ways to improve this intricately linked hierarchical system for surveillance of infectious diseases as well as ways to reorganize the system to take advantage of advances in communications technology and to respond to infectious disease threats that increasingly cross county and state boundaries. Military surveillance systems and the United States' participation in global surveillance activities were beyond the scope of this project.

Below we identify a series of critical gaps that need to be addressed to ensure the population is adequately protected against infectious disease threats. These gaps fall into three categories:

- Gaps in the core capacity of the key entities involved in conducting surveillance of infectious diseases;

- Gaps in the flows among the entities involved in surveillance of infectious diseases; and

- Gaps in the structures that support surveillance.

We describe each of these gaps below.

Gaps in the core capacity of the key entities involved in conducting surveillance of infectious diseases. This type of gap refers to the resources within state and local health departments, the CDC, public and private laboratories, and provider systems that allow each entity to perform its role in meeting the goals of surveillance.

Our study identified the following specific gaps:

- No clear set of standards exist that defines the critical surveillance needs and associated capacity requirements at all levels of the system. While some efforts have been made to define standards for public health laboratories and food borne diseases, no comprehensive and systematic effort has been undertaken.

- Local capacity is not sufficient to ensure adequate performance across the eight goals of surveillance. Staffing, skill levels, technological capability, and training are uneven across the country, leaving some populations less well protected from infectious disease threats than others. Local level public health officials need support from state health departments and the CDC to develop needed skills, to back-up local level staff during outbreaks, for technological support, and to provide guidelines for how to handle various situations. For example, after the report of a case, public health staff often have to contact the provider and or the affected individual to obtain complete information about the clinical picture, demographic and risk information, treatment information, contacts who may be at risk and may require testing or prophylactic treatment, etc. A recent case of tuberculosis identified in a school bus driver required public health officials to identify and test over 100 children who may have been exposed. This investigative activity is a key, very labor intensive part of the surveillance process that often falls through the cracks because of lack of local capacity. Without it, public health response to individual cases is difficult and most case reports will be missing key information that make the data less useful for analysis at higher levels in the system.

- Staff capacity at the state and large local level[2] is frequently not adequate to support ongoing collection and analysis of surveillance data to detect changes in the epidemiology of infection, to evaluate surveillance efforts, to plan interventions, and to set priorities. For example, lack of staff capacity to conduct mosquito surveillance in New York City contributed to the delayed recognition of West Nile Virus.

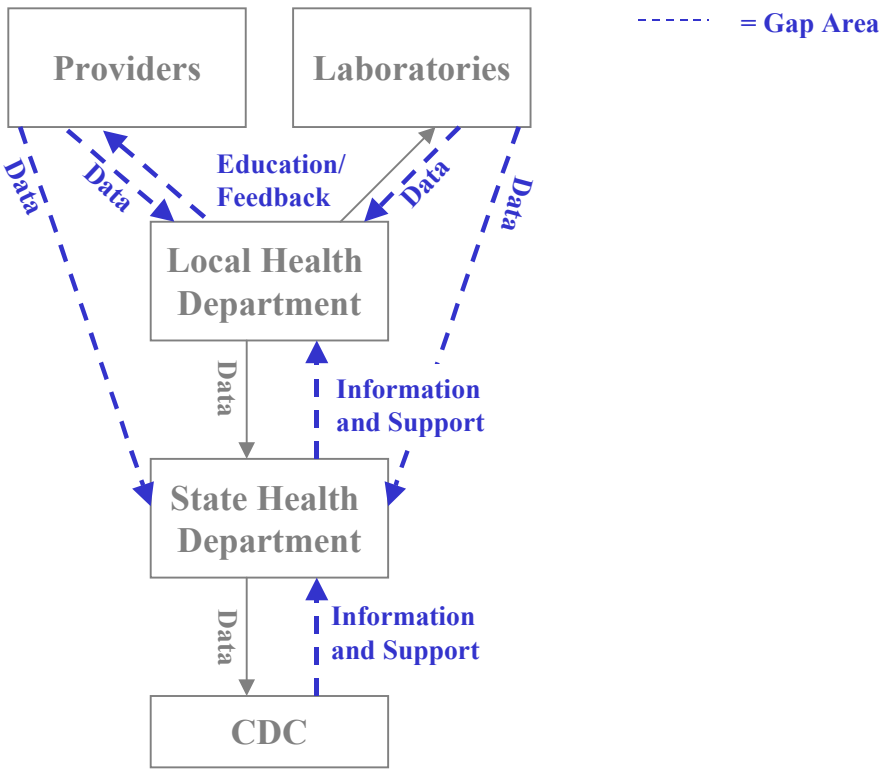
[2] Large local refers to cities and metropolitan areas.

- Computerized decision and analytic support tools have not been developed to their fullest potential to support infectious diseases surveillance activities. For example, the military currently has the capability to collect patient data electronically on a real-time basis from field personnel. This data is fed into computer software that can detect when the occurrence of disease is outside its expected frequency. While this system is not currently broadly applicable to public health, it illustrates the potential utility of electronic medical record data for surveillance within defined populations.

- The public and private laboratory capacity supporting surveillance has eroded. Public health laboratories are perceived to be behind the private sector in terms of technology development, dissemination, and adoption. Meanwhile, private laboratories, which focus on clinical rather than broader public health needs, face cost pressures that have encouraged fewer and less specific tests. Private laboratory consolidation into large regional or national facilities has made the current practice of reporting separately to each jurisdiction cumbersome and impractical.

Gaps in the flow of data and information among the entities involved in surveillance of infectious diseases. As outlined above, surveillance of infectious diseases involves a series of data and information flows among the numerous entities involved in surveillance. Exhibit 6 depicts the gaps pertaining to these flows.

EXHIBIT 6: GAPS IN FLOWS AMONG ENTITIES



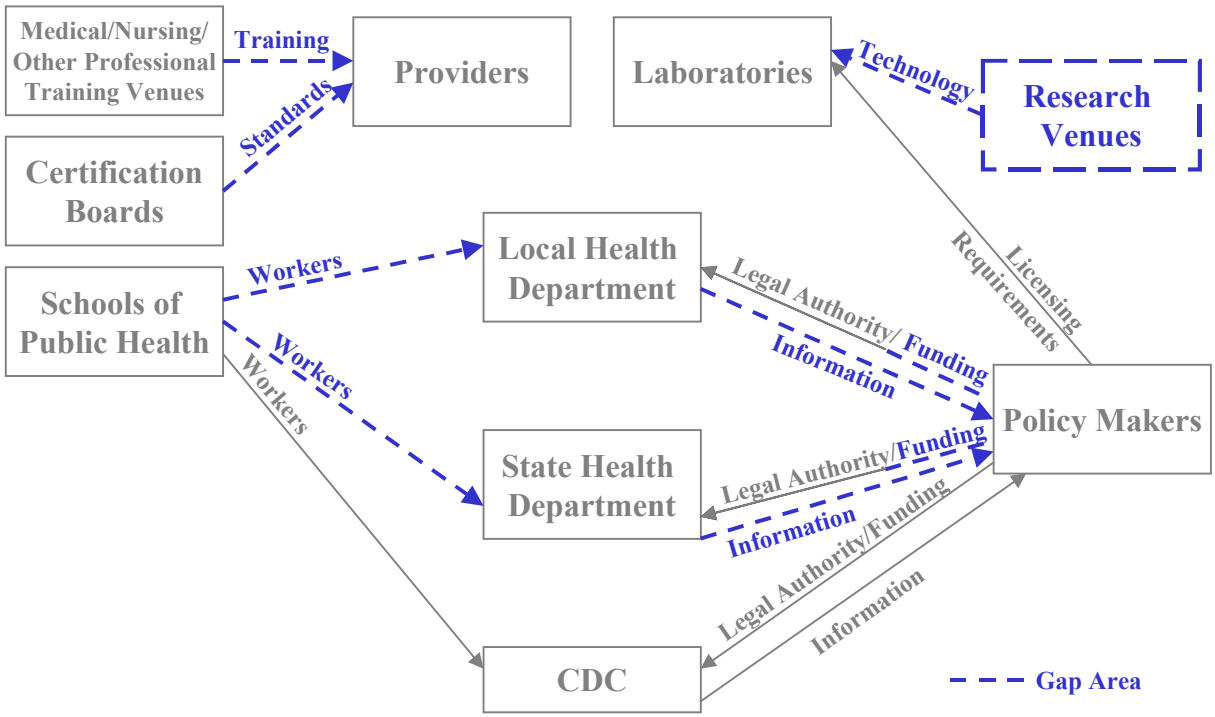
Our analysis identified a number of critical gaps in these flows:

- Provider and laboratory reporting of infectious diseases is incomplete and not timely. Case reporting is a critical foundation for infectious diseases surveillance; full participation from the provider community is a necessary component of a functional surveillance system under current data flow arrangements. Estimates of completeness of reporting range from 6% to 90% for many of the common notifiable diseases. Reasons given by providers for not reporting include: assumed that the case would be reported by someone else; unaware that disease reporting was required; do not have notifiable-disease reporting form or telephone number; do not know how to report notifiable diseases; do not have copy of list of notifiable diseases; concerned about confidentiality; concerned about violation of doctor-patient relationship; reporting is too time-consuming; and absence of incentives to report.

- A great deal of data flows through the system but feedback and analysis need to be more effectively packaged and disseminated from the CDC to states and locals, from states to locals, and from public health venues to the clinical delivery system. Better feedback would help to engage the delivery system in infectious diseases surveillance.

Gaps in the structures that support surveillance. As described above, the core system is supported by educational institutions, accrediting and licensing agencies, the public and private research establishment, and policy-makers. Exhibit 7 depicts gaps pertaining to these structures.

EXHIBIT 7: GAPS IN STRUCTURES THAT SUPPORT SURVEILLANCE



Gaps identified with respect to these supporting structures include:

- Public health workers specifically trained to do infectious diseases surveillance are perceived to be in short supply.

- Training programs do not adequately educate clinical health professionals on their role in surveillance.

- Research and development of new laboratory technology is focused on clinical rather than public health applications. Advanced laboratory technology that is available to support surveillance needs to be disseminated and adopted more rapidly.

- Public health misses opportunities to communicate the importance of surveillance to policy-makers and the media. A better understanding of surveillance among these constituencies would help ensure adequate funding and a rational legal framework to support it.

In addition to these specific gaps in the system, we identified a number of cross-cutting issues that need to be addressed. These include:

- ***Information technology.*** Information technology offers opportunity for improvement across many areas, but significant obstacles exist to its widespread deployment. Support is lacking for existing technologies and current capabilities are uneven across states, localities, and disease areas. Lack of data standards and issues of privacy, confidentiality, and security must be resolved before systemic solutions can be implemented.

- ***Widespread innovation but limited sharing.*** States, localities, and disease areas within CDC are developing multiple solutions to the same problems around data capture, analysis, and transmission. For example, many states are developing their own systems to integrate data across disease areas. There is a missed opportunity to share information and capture and disseminate lessons learned.

- ***Categorical funding.*** The historic patterns of categorical funding have impeded the development of a basic surveillance infrastructure capable of meeting the most critical disease threats. The surveillance infrastructure is fragmented and focused on specific diseases rather than on the broad range of threats that face a given population. This fragmentation is both a function of how Congress has funded the CDC and how CDC allocates money to states and localities. As a result data systems are incompatible and capacity is uneven across disease areas. The flexibility of federal funding for emerging infections and bioterrorism has been widely praised for its contribution to core capacity, but critical gaps still remain.

Public Health Threats Posed by Gaps in the System

Numerous gaps in U.S. capabilities for conducting infectious diseases surveillance leave the health of the public susceptible to a wide array of threats. The current categorical system is unprepared to deal with some of the most urgent concerns facing the public health system.

Specifically, the experts who contributed to our research identified four potential threats in particular:

- ***Emerging Infections.*** These include new or resurgent infectious diseases. New Variant CJD (the human disease associated with bovine spongiform encephalopathy or "mad cow" disease) is one recent example. These infections often take providers and public health officials by surprise, leaving the medical and health care communities unarmed to defend against them in the short term. Rigorous surveillance is needed to identify and control such diseases before they become widespread.

- ***Drug Resistance.*** Many infectious pathogens are renowned for their ability to mutate to accommodate changes in the environment. One particularly devastating type of mutation enables pathogens to become resistant to antibiotics. When this situation occurs, pathogens can thrive despite medical treatment. Drug resistant tuberculosis has emerged as a major problem around the world. Surveillance is critical to identifying changes in pathogens so that drug development can keep pace with evolving pathogens.

- ***Bioterrorism.*** The concept of bioterrorism has received a great deal of attention in recent months by legislators, government officials, and the press. It is defined as the deliberate spread of infectious diseases. Bioterrorism events could be potentially devastating – they are unpredictable and their effects could easily overwhelm our medical care system. Strong surveillance is needed to identify these events at the earliest sign in order to trigger an immediate response. Bioterrorism falls outside the scope of most of our current surveillance efforts in that resulting infectious illness can not be defined in categorical terms.

- ***Pandemic Influenza.*** Experts fear the antigenic shift to a new pandemic strain of influenza such as that which occurred in 1957 with the introduction of the Asian strain and in 1968 with the introduction of the Hong Kong strain. In each of these instances there was a significant increase in illness and deaths. The essential role of surveillance is to recognize the antigenic shift as quickly as possible so that the new strain can be incorporated into the vaccine.

While these examples represent those threats of greatest concern to surveillance experts, a myriad of smaller-scale, every day threats also persist which can only be addressed through strengthened surveillance capacity.

INVESTMENT PLAN

Based on this assessment, we have developed a set of recommended investments to address the most critical gaps in the nation's core capacity for infectious diseases surveillance. This plan includes calculated investments to be phased in over time. Some investments will improve capacity within its current structure and organization. Other investments will move toward a new system for surveillance which is less fragmented and which more heavily leverages the technological advances that have been made in systems to collect, analyze, and disseminate data and information. The investments recommended present a mix of local and top down solutions. In some areas the path to improvement is somewhat clear; it only involves an infusion of

resources to make headway. In some areas the investments involve demonstration or prototype efforts to experiment with ways to address key gaps. These types of efforts address problems for which solutions have not yet been developed. In other areas we recommend additional studies or panels to better define a problem, set standards, or involve key constituencies in proposing solutions to a particularly thorny or technically challenging issue. This report does not recommend specific dollar amounts to support each investment priority.

Many of the investments described below are in line with CDC priorities for FY2000 and 2001, however, implementation of this plan would require a substantial increase in funding. Funding for these initiatives could come from a variety of sources including the federal government, state and local governments, foundations, and the delivery system. This document outlines a five-year investment strategy but funding for many of the recommended actions will need to continue beyond the time period of this plan. ***Sustained investment will be required to maintain the gains in core capacity made as a result of this plan.***

An important cross-cutting investment priority involves information technology (IT). Effective information gathering and processing is the foundation on which effective surveillance is built. Rather than isolate IT as a single priority, we recommend specific information technology investments as parts of the other recommended investments in order to provide critical tools to achieve specific objectives. These investments need to be tightly coordinated with the CDC's National Electronic Disease Surveillance System to ensure that any technology developed under this investment plan adheres to national standards for data collection, management, transmittal, and analysis. Issues of privacy, confidentiality, and security of health care data are of paramount importance, but these are larger issues that need to be dealt with for the entire health care industry, hence are not addressed comprehensively in this investment plan.

Recommended Investments

Below we present a three pronged strategy for improving core capacity for infectious diseases surveillance. Each of the three prongs has two major components along with a package of specific activities that relate to each component. These priority investment areas are:

1. ***Improve State and Local Preparedness to Identify and Respond to Infectious Disease Threats.***

   A. *Improve Local Capacity to Conduct Surveillance of Infectious Diseases.*

   B. *Increase Staff and Technological Capacity for Epidemiological Analysis at the State and (Large) Local Level.*

2. ***Engage the Health Care Delivery System and the Public as Partners in Infectious Diseases Surveillance.***

A. *Better Engage the Health Care Delivery System in Infectious Diseases Surveillance.*

B. *Increase Public Support for and Engagement in Programs to Protect the Community from Infectious Disease Threats.*

3. ***Enhance Public and Private Laboratory Support for Infectious Diseases Surveillance.***

A. *Better Coordinate Public and Private Laboratory Capacity to Support Infectious Diseases Surveillance.*

B. *Speed Development and Dissemination of Lab Technology to Support Infectious Diseases Surveillance.*

Below we present the major objectives for each component of the investment plan within the three priority areas. We then outline a series of specific investments to address each area. While each of the three areas was deemed by the expert panel to be critical for investment, the level of urgency of the specific investments varies. We asked the expert panel to prioritize each of the individual investments. From this exercise we sorted the investments into three levels of priority:

Level 1: Address immediately

Level 2: Address within two years

Level 3: Address within five years

The level one priorities tend to relate to the first steps in the surveillance process—including reporting, case investigation, and analysis — that lead to identification and assessment of threats to the health of the public and first order response. These steps require a strong interface between the delivery system (including laboratories) and local public health authorities and are critical to all that follows. This public/private interface represents the place where expert panelists and key informants thought breakdown most often occurs. Steps performed at this level are the most time-critical, especially in the event of a public health emergency such as a bioterrorism event or contaminated food or water. These investments would likely have a direct and immediate impact on the nation's capabilities to detect and respond to outbreaks.

The level two priorities relate more to the routine analysis of surveillance data and the research that supports the development of laboratory technology to support surveillance. Ongoing analysis of data is important to detect changes in the epidemiology of disease, assess health status, and assist in health planning. Development of laboratory technology is important to ensuring rapid and accurate diagnoses. These investments are important, but were deemed less time critical than the level one investments.

The level three priorities relate to training, education, and feedback. These investments would enhance communication around the importance of surveillance and contribute to both public and provider engagement as well as help to strengthen the surveillance workforce. These investments would have less of a direct and immediate impact on surveillance.

Overarching Management Structure *(Level 1)*

In addition to the specific investments outlined above and described in detail below, an overarching management structure is essential to ensure the activities supported by this plan are coordinated with other efforts to improve the surveillance infrastructure, and to disseminate the results of successful demonstration projects. A number of efforts are currently underway that address various aspects of the gap areas uncovered by this study. For example:

- The National Electronic Disease Surveillance System is addressing the issue of data and software standards and supporting the development of standardized analytic tools and complementary electronic information systems to automatically gather data from a variety of sources on a real-time basis.

- The Epidemiology and Laboratory Capacity Program is supporting various efforts to improve state and local capacity.

- The Emerging Infections Program is funding collaborative projects to integrate information from varying locations and populations about emerging diseases.

- The Health Alert Network is investing in local capacity building with a communications technology focus.

- Various other CDC initiatives are taking different approaches to shore up the system to deal with bioterrorism and other biological threats.

States and localities are developing their own solutions to many of the problems identified in this study and some of these efforts may represent "best practice" approaches that could be built upon. The Veterans Health Administration, the military, the U.S. Department of Agriculture, Food and Drug Administration, and the Department of Justice also have surveillance related initiatives.

One of the goals of this investment plan is to increase integration across the myriad of surveillance "systems" that currently operate. An overarching structure that can centrally manage this investment plan and serve as a clearinghouse for surveillance-related project information is a critical component. This office should work to coordinate the various organizational bodies and demonstration projects with each other and with other surveillance efforts and make sure that all investments are knit together to ensure a concerted, meaningful approach. This office should ensure the results of demonstration projects funded through this investment plan are evaluated, disseminated, and, when indicated, adopted on a national basis. It should also track other initiatives outside of this investment plan for potential dissemination and adoption.

This office should work closely with an advisory committee composed of representatives from CDC, state and local health departments, public and private laboratories, the provider community, and other stakeholder groups. An analogous structure is the National Committee on Vital and Health Statistics which serves as a public advisory body to DHHS in the area of health data and statistics.

This overarching structure will also manage additional research activities in areas where the expert panel felt that more analysis was needed before moving forward with specific investments.

Below we describe in detail the investment objectives and approach for each component of the three pronged strategic approach to improving core capacity for infectious diseases surveillance.

1. Improve State and Local Preparedness to Identify and Respond to Infectious Disease Threats.

A. Improve Local Capacity to Conduct Surveillance of Infectious Diseases

Local public health capacity represents the frontline in investigating and responding to outbreaks. Local jurisdictions receive reports from providers and are responsible for investigating reported cases, determining the source of infections, identifying the mode of transmission, and tracing contacts to identify other individuals potentially affected. These steps require interviewing people, analyzing data, assessing the nature of the public health threat, and coordinating the resources necessary to respond to public health emergencies.

Local capacity was identified as one of the most critical gaps in the public health infrastructure for surveillance of infectious diseases. This includes both local health departments and state health department personnel who work at the local level. A panel of experts, which included state and local health officers and who served as advisors to this project, rated local level performance relative to the goals of surveillance as "inadequate". Five goals of surveillance stood out as both high priority and low performance. These included:

- Detecting outbreaks;
- Detecting changes in the epidemiology of infection;
- Assessing the health status of the public;
- Evaluating prevention and control interventions; and
- Assisting in health planning.

Inadequate staffing, lack of skills, unavailable or under-used technology, and insufficient support from other levels of government are key impediments to effective performance at the local level. Interviews indicated high variability in resource levels and capabilities across local jurisdictions. Since local public health capacity tends to be organized at the county level, there are large disparities in the numbers of people in each jurisdiction. Many jurisdictions by themselves do

not have the critical mass of population necessary to support the maintenance of surveillance and epidemiologic skill levels and basic functions such as coverage 24-hours a day, 7 days a week. There are few examples of consolidation or coordination of capacity across jurisdictions to ensure that all communities are served by some level of surveillance capacity.

Many outbreaks are first detected when a concerned physician calls a public health official. Assessing and responding to outbreaks often requires the provider and public health communities to work closely together. In order to ensure this partnership works effectively, health departments need to have a strong relationship with the provider community at the local level and be perceived as credible, helpful, and responsive. That relationship is critical to the flow of information from the clinical care delivery system to the public health system. This relationship depends on sufficient capacity to conduct outreach and education of the provider community—another critical performance gap identified in our research. Lack of local public health credibility with physicians was cited as an impediment to engaging the delivery system in surveillance activities.

Capacity must also be available for active surveillance where public health officials actually go out and look for cases of disease in people or monitor non-human reservoirs of disease such as animal or insect populations or water supplies. West Nile virus stands out as an example of where a local health department did not have sufficient resources to monitor key reservoirs of disease—local bird populations and mosquitoes. This type of monitoring can be an effective way of identifying a disease before it shows up in humans. In the case of West Nile Virus, once the disease was reported, significant resources had to be pulled from other areas and other levels of government to identify its cause and take the necessary preventive steps.

Ensuring local capacity is adequate to meet the most important goals of surveillance is the focus of the first component of this investment priority.

Investment Objectives

The objective of priority one is to improve the competency, performance level, and credibility of local level public health officials with respect to infectious diseases surveillance such that:

- Staffing is sufficient to perform key functions;
- Requisite skills and training are in place (e.g., surveillance, case follow-up, outbreak investigation, epidemic response, disease specific knowledge);
- Requisite technological capacity exists (high speed internet access, broadcast fax capability, e-mail, key software packages, technological support);
- Technology conforms to the national standards for data collection, storage, and transmission under development through the National Electronic Disease Surveillance System (NEDSS);
- A 24/7 coverage level exists for all populations;

- Localities can meet acceptable response times for initiation of case investigations and standards for information transfer (content, timeframe);
- Localities can meet performance standards for provider and community outreach/education;
- States and the CDC provide a high level of support to assist localities in meeting performance standards;
- Clusters of local health departments are encouraged to work together to ensure a sufficient population base exists to support basic infrastructure and maintain skill levels;
- The emphasis on improved infectious diseases surveillance does not diminish the effectiveness of other necessary public health functions.

Investment Approach

Level 1: *Grant/Technical Assistance Program to Improve Local Capacity*

We recommend annual investments through a grant/technical assistance program that would work with (and channel dollars to) state/local partnerships to:

- Create and communicate performance and capacity standards for infectious diseases surveillance at the local level using a collaborative approach;
- Assess their own performance relative to these standards;
- Assist localities to acquire the staffing, skills, and technology required to meet these standards;
- Create federal, state, and/or regional support structures to assist localities in meeting these standards including back-up staff, guidelines, distance based-learning technology and programs, technical support, and training;
- Reward cross-jurisdictional collaboration;
- Evaluate and disseminate results of above efforts.

This program would supplement the current investment in the Health Alert Network (HAN), a program that is investing federal dollars to develop local health department capacity as part of a national effort to ensure preparedness for bioterrorism and other biological threats. This program would address a broader set of performance goals with less relative emphasis on technology and more on staffing, skill levels, and cooperation across jurisdictions. This grant program, however, should be tightly coordinated with HAN to ensure that jurisdictions are not funded twice for the same capacity building efforts. Performance standards should include conformity to nationally developed standards for data collection, storage, and transmission.

This program should also be coordinated with the NEDSS efforts to facilitate private sector engagement through the adoption of data standards, the creation of systems architecture, and the use of hardware/software for regional/national routing of electronic surveillance information.

A key component of this program will be the development of performance standards and the assessment of local level performance relative to these standards. Performance standard development should be coupled with a critical assessment of what and how much capacity is needed at what levels of government for areas of different sizes and population density. This assessment should be conducted with the intent for consolidation across the country of some aspects of surveillance. ***Development of these standards, however, should not in any way delay getting funding to state and local health departments to begin improving capacity.***

Development of these standards should be collaborative rather than prescriptive with states and localities creating standards with support from the CDC, the National Association of County and City Health Officials, the Association of State and Territorial Health Officers, the American Public Health Association, the Infectious Diseases Society of America, and the Council of State and Territorial Epidemiologists. Representatives of these organizations will form a national steering committee which will advise the grantee organizations on the development of standards. Part of the grant money should go to support a series of committee meetings to work towards surveillance performance standards that build on the work of the National Public Health Performance Standards Program. We recommend that funds be given to begin the performance assessment and improvement process within the first year of the project based on an initial set of broad performance goals.

This national steering committee should develop prototype standards and assist state/local partnerships in customizing these standards to reflect local realities. Part of the role of this national committee should be to craft an overarching, coherent, flexible guiding information architecture for surveillance data. This group should look at issues such as whether data on all diseases of public health importance need to be collected in all localities and which surveillance techniques are appropriate given the surveillance goals for specific diseases (e.g. for which diseases would the use of sentinel surveillance networks be effective). This guiding architecture would support the development of a nationally coherent, rather than fragmented, surveillance system and ensure that scarce resources are used most effectively.

Suggested parameters of the grants/technical assistance programs are as follows:

- Eligible applicants for grant awards will be state/local partnerships, single local jurisdictions serving a population of 250,000 or more, multi-city or county partnerships that together serve a population of 150,000 or more, or regional partnerships including multiple states and localities.

- Preference should be given to partnerships, especially those that include small jurisdictions among their members.

- Investments should be targeted to areas that have the most need. Priority should be given to organizations that have not received funding for basic infrastructure improvement in the recent past.

- Grant-writing support should be given to potential applicants who fall below a certain public health funding floor. Efforts will need to be made to ensure this floor reflects consistency in how expenditures are calculated.

- Seventy-five percent of the funding should go to local jurisdictions to hire and train staff and/or enhance their technological capabilities. Fifteen percent of the funding should go to state or regional activities that directly support local capacity building efforts (e.g. state level staff that can provide training or technical support, distance learning sites to be shared among counties, etc.). The remaining ten percent of the funding should go to the effort supporting the development of performance standards and in later years the assessment of performance relative to these standards.

- Funding past the initial year should be tied to planned and actual performance improvement.

- Local or state matching funds could be required.

Timing

Year 1: National steering committee develops broad performance goals within first six months and begins moving towards more detailed standards. Individual grantees participate in standard development activities at the national level and within their own states/regions to customize these standards to local realities. Initial capacity building investments should be made where clear gaps exist during the first year, but by the end of the year each jurisdiction should have a sense of where they are relative to the more detailed set of standards. A performance improvement plan for moving towards meeting those standards could be required to receive year two funding. Efforts will be concurrently evaluated and the results disseminated across all grantee organizations.

Year 2: National steering committee focuses on assessing surveillance program needs across grantee organizations and developing training programs, guidelines, technologies, and support structures (e.g., back-up staff, information technology support, technical assistance, etc.) to help localities meet these needs. Training programs and support structures could be developed at the state, regional, and/or federal level. Localities would continue to build their capacity through increased staffing, enhanced technology, and/or training and skill development. Efforts will be concurrently evaluated and the results disseminated across all grantee organizations.

Year 3: Implement training programs and support structures to continue enhancing local capacity.

Years 4 and 5: Continue funding local capacity and support structures, contingent on progress in meeting standards. Decrease funding to original partnerships to support maintenance of capacity as opposed to standards development, capacity assessment, and capacity development. If funding

levels permit, expand program to include additional partnerships. Continue evaluating efforts and disseminating results across all grantee organizations.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Establish broad performance goals	—				
Award grants	X				
Establish detailed performance standards	—				
Develop performance improvement plans	—				
Build capacity at local level	—	—	—	—	—
Develop support structures		—			
Implement support structures			—	—	—
Evaluate results	—	—	—	—	—
Award additional grants			X		

B. Increase Staff and Technological Capacity for Epidemiological Analysis at the State and (Large) Local Level

A recurring theme in our research was the lack of useful information to guide decision-making, despite the relative wealth of data. Key informants and expert panelists pointed to limited capacity for epidemiological analysis within many state and large city/county health departments. This issue was perceived to be both a staffing and technology issue. The root of the staffing problem is somewhat unclear—some of those interviewed reported difficulty finding appropriately trained individuals to fill open positions, some reported lack of funds to create positions dedicated to analysis, and others reported that salaries and benefits offered by public health agencies were not competitive with other opportunities available to epidemiologists. Additionally, respondents felt that existing analytic and decision-support technologies are underutilized to support infectious diseases surveillance. Whatever the root issues, the lack of epidemiological capacity impairs the ability of health departments to meet critical goals of surveillance. ***We recommend additional research to determine the root of the problems identified before substantial investments are made.***

Priority goal areas where performance falls short due to lack of analytic capacity include:

- Detecting changes in the epidemiology of infection;
- Assessing the health status of the public;
- Evaluating prevention and control interventions; and

- Assisting in health planning.

Turning data into information was also noted as a critical component of efforts to better communicate the importance of surveillance efforts to key constituencies such as providers, the media, community leaders, and legislators at all levels of government.

The second component of investment priority one addresses the staffing issue as one of both supply and demand. The technology issue is one where experimentation will be required to move forward because the technology exists—e.g. data mining, pattern recognition, GIS, etc.—but has not yet been applied systematically to aid surveillance efforts.

Investment Objectives

The overall objective of this investment priority is to increase the capacity for epidemiological analysis at state, regional, and populous local levels by:

- Increasing the number of skilled epidemiologists working at the state and (large) local level to improve core capacity to:
  - Detect changes in the epidemiology of infection,
  - Evaluate prevention and control interventions,
  - Inform priority-setting and communicate priorities effectively to providers, policy-makers, and the media;
- Improving the technology available to support the analysis of surveillance information through:
  - Decision-support systems and analytic software,
  - Efforts that integrate data across disease areas and/or jurisdictions;
- Increasing the number of epidemiologists entering the public health workforce and improving retention of current staff.

Investment Approach

This investment approach will include three major streams of activity. First, we recommend a grant program that would provide funding to states, large localities, or regional partnerships to expand or develop epidemiology programs. Second, we recommend the funding of development grants to build better analytic tools. Finally, we recommend working with selected educational institutions to increase the number of epidemiologists with an interest in infectious diseases surveillance entering the workforce.

Level 2: *Epidemiology Program Development Grants*

We recommend a grant program that would fund states, large cities, and/or regional partnerships to expand or develop epidemiology programs. Regional partnerships could be composed of multiple counties within states or multiple states. The funding would go to increase the staff resources devoted to epidemiological analysis. Individual grantees could apply to add up to three positions. The funding could be used to hire masters, PhD, or MD/PhD prepared epidemiologists or to hire analytic or administrative staff to support an epidemiology program. This grant program should be coordinated with the Epidemiology and Laboratory Capacity (ELC) program. The ELC program is funding 43 state/local health departments to enhance health department capacity to detect, investigate, prevent, and control infectious diseases.

Level 2: *Grants to Develop and Disseminate Prototype Tools to Support Analysis of Surveillance Data*

One of the key gaps noted in the current system for infectious diseases surveillance is the lack of technology and methodologies to support analysis and decision-making at state and local levels. Our interviews and site visits indicated that development efforts are occurring in this area but that successful efforts have not been widely disseminated. Investment resources should encourage thinking outside the box to support a move away from a "report" as the necessary first step and toward automated systems that flag unusual patterns or sentinel events. We recommend that investment dollars go both to identifying and disseminating existing efforts as well as developing new prototype analytic tools and methods to support analysis of surveillance data. Development grants would be given to individual health departments, or to partnerships between health departments and software developers or academic institutions or other interested parties. The common denominator would be the involvement of a public health department. We recommend active involvement of CDC staff to ensure tools are built to conform to data standards developed through NEDSS. These tools might include:

- Further development of pattern recognition methodologies and supporting software;
- Applications involving geographical information systems;
- Improved tools to automatically identify when an event or cluster of events exceeds its expected frequency including automated software agents as well as development of the algorithms that would underlie those agents;
- Remote scanning of distributed databases (e.g., monitoring pharmacy data to detect surges in disease or detect multi-drug resistant tuberculosis (MDRTB) cases unreported to health officials);
- Technology to integrate data across categorical disease areas to support coordinated surveillance activities and methodologies for analyzing such integrated datasets.

Tools developed would be evaluated and those that proved useful would then be disseminated on a national basis.

Level 3: *Encourage Students to Pursue Careers in Epidemiology and Infectious Diseases Surveillance*

Staffing is one of the largest problems faced by health departments. In particular, as discussed above, health departments are experiencing shortages of individuals trained in epidemiology with an interest in surveillance. Increasing investigative and analytic capacity in health departments is critical for achieving the goals of surveillance. The ability of health departments to obtain funds to hire epidemiologists is addressed above; the flip side of this problem, however, is ensuring that there are sufficient numbers of trained individuals to fill positions.

We recommend making investments to encourage more people to enter the field of epidemiology and follow a career path in surveillance of infectious diseases:

- Provide students entering schools of public health scholarships that carry service requirements;
- Fund surveillance field placements for trainees and staff in schools of public health at the state and local level.

These investments have a number of benefits. First, the scholarships make public sector employment a more financially attractive option. Second, exposure to opportunities in local and state health departments (through both the scholarship requirement and field placement) may increase the perceived attractiveness of such positions. Finally, expertise in this field tends to concentrate at the CDC (where field placement is routine) as well as schools of public health. Offering paid opportunities through short-term field placements for public health faculty and other professionals and students would spread expertise to needed areas.

Level 3*: Model Curricula Development*

We also recommend investing in an effort to develop model infectious diseases surveillance curricula for epidemiologists. Many experts contacted during our research consider training offered in epidemiology at schools of public health to be inadequate. This investment would fund a panel of surveillance experts (from both health departments and academia) to create a new curricula designed to train students of epidemiology in methods, field work, and analytics. A coordinating organization, such as American Public Health Association (APHA), the CDC, or a school of public health, through which funds would be funneled, would convene the panel and disseminate the new curricula to schools of public health. This panel would also need to address the issue of competition for "space" in the overall educational program.

Results of each of these investments should be evaluated and disseminated.

Timing

By the end of year 2 the epidemiology program development grants and the awards to develop prototype analytic tools would be awarded to an initial set of grantees. A round of scholarships

and field placements would also be awarded beginning in year 3. A panel for the development of school curricula would be convened and start their initial work during year 3, as well.

During the later years of this investment approach an evaluation of the various grant and field placement programs would be conducted and new grants awarded. Results would then be disseminated.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Epidemiology program development grants					
– Award grants					
– Develop and maintain programs					
– Evaluate results					
Prototype analytic tool development					
– Award grants					
– Develop tools					
– Evaluate results					
– Disseminate					
Supply-side efforts					
– Scholarship program					
– Curricula development					
– Field placements					
– Evaluate results					
– Disseminate					

2. *Engage the Health Care Delivery System and the Public as Partners in Infectious Diseases Surveillance.*

A. Better Engage the Health Care Delivery System in Infectious Diseases Surveillance

An effective system for surveillance of infectious diseases requires a partnership between the health care delivery system and public health programs. The diagnosis and subsequent reporting of disease is the first step in the surveillance process, and according to our research, the place where breakdown most frequently occurs. The problem was most often characterized as the failure of providers and laboratories to meet their obligations to report, and knowledgeable

experts were uniformly pessimistic that either stronger legal requirements or stronger requests would promote significantly better voluntary reporting.[3]

Our research identified a number of specific barriers to provider reporting:

- Lack of knowledge and education of providers and health care systems about their role in surveillance;
- Provider and system confusion about when and/or to whom to report;
- Lack of information systems in healthcare provider organizations that facilitate reporting;
- The time involved in reporting, especially for providers who might have to report to multiple jurisdictions each with its own requirements;
- Absence of incentives for the healthcare delivery system to support surveillance; and
- A failure on the part of public health to provide feedback to providers on the results of their efforts, including feedback that has direct clinical implications for treatment.

Key informants and site visit participants noted that targeted outreach efforts had yielded some improvement in reporting, but they felt that a real solution would require a combination of efforts to improve the old system and efforts to develop entirely new approaches. These new approaches involve recasting the issue as one not of provider reporting but as one of information flow between a broad range of potential sources of clinical data—individual providers, health care systems, laboratories, pharmacies, health plans, etc.—and the public health system.

A revolution is currently taking place in the information technology that supports clinical care delivery. Surveillance interests need to be represented as new systems and standards are developed. Attempts to change provider behaviors will only be effective if efforts are rooted in how care is delivered and how clinical information is captured at the point of service. Hence the recommended investment strategy involves several streams of activity aimed at both enhancing the traditional system of provider reporting as well as exploring new opportunities to get at key clinical data and create a mutually beneficial and more integrated relationship between the clinical and public health communities. In addition to primary focus on solutions that will better integrate the medical and public health systems, we also recommend supplementary educational initiatives aimed at providers.

Investment Objectives

The overall objective of this component of priority two is to effect a change in the provider culture through better integration of the medical and public health systems and to move to a standard of practice where infectious diseases surveillance is seen as an integral part of the role

[3] For purposes of this investment plan, we will address issues specifically related to laboratory reporting in investment priority three.

of a provider. The public health system should engage the health care delivery system in surveillance of infectious diseases such that:

- The transfer of information from clinical to public health venues is quick, easy, and less burdensome to health care providers;
- The information received is timely and complete;
- The delivery system understands the importance of surveillance activities in general and the role of clinical data in support of surveillance efforts;
- The delivery system feels rewarded for its participation in surveillance and receives feedback that has clinical utility.

Investment Approach

The first stream of activity deals with ways to make reporting of infectious diseases easier for health care systems and providers and to better leverage existing clinical data sets in surveillance activities. Second, we recommend a stream of activities aimed at better engaging the delivery system by providing clinically useful information and feedback to providers from surveillance. Third, we recommend a national effort to better utilize an existing resource, infection control professionals within hospitals, to support surveillance efforts. The final stream of activities focuses on efforts to ensure the care delivery system appreciates the importance of clinical data to infectious diseases surveillance efforts and understands the role of the individual provider in supporting surveillance efforts.

Level 1: *Investments to Improve Ease and Efficiency of Reporting*

The first investment focuses on making it easier and more efficient for providers to communicate with and report to public health authorities. Because this is an area where few specific solutions have been developed and tested, we recommend demonstration projects for regions, states, or large localities. These projects would work to improve information flow in a wide variety of ways. The recommended approaches involve software development to make reporting quick and easy as well as a rationalization of reporting requirements across jurisdictions. Ideally the systems developed to facilitate reporting should build upon the systems that support care delivery.

Currently organizations are developing systems that can produce the encounter level data required by Health Insurance Portability and Accountability Act (HIPAA). The industry is creating the Health Level 7 standards to govern data collection, transmittal, and analysis. Meanwhile organizations are working to move away from paper-based transactions and documentation of clinical information. Surveillance information systems need to be integrated with clinical information systems in order that surveillance becomes a standard of practice.

The ultimate goal of this investment would be to create and deploy automated, easy-to-use, rapid reporting systems nationwide based on national standards. These systems would need to integrate

developments in surveillance methodology with information transfer and analysis. The CDC is currently working to develop a National Electronic Disease Surveillance System (NEDSS). Part of this investment will go to a limited number of state-based demonstration projects to link the health care delivery system to public health. A major thrust of this program is to develop standards for data collection, management, transmittal, analysis, accessibility, and dissemination. These standards will address key issues such as privacy, security, and confidentiality. In order to ensure substantive progress in this area over the long term and ensure all efforts adhere to NEDSS standards, we recommend an office be designated within CDC to manage and evaluate new and existing investments and ensure that solutions developed are replicated on a national basis. Coordination of these efforts with NEDSS will help ensure that the demonstration projects developed under this program will be broadly applicable to other jurisdictions and help meet a long-term goal of reduced system fragmentation.

Preference in funding would be given to partnerships that include at least two of the following: a public health department, a provider system, a software vendor, a health plan, a pharmacy benefit manager, or another public or private data repository OR a collaboration of multiple state health departments. Some of the investment dollars could be used to convene a multi-disciplinary taskforce including large provider systems, HMOs, labs, public health departments and others to generate ideas on new approaches to collecting surveillance data.

Examples of demonstration projects might include:

- *Development of web- or modem-based, interactive tools for provider reporting.* Internet and web-based technologies offer tremendous potential for easing the burden on providers of reporting cases of infectious diseases. Additional benefits of using this technology will likely include faster and more complete reporting.

  A website used for reporting could have other advantages. For example, in order to better engage providers, this website could post user-friendly statistics and reports that would be of interest to providers or could return up-to-date bulletins, links to guidelines, or educational content related to the condition reported. The site could be an educational venue, as well as provide information about public health and infectious diseases.

  Ensuring appropriate means to protect privacy, however, will need to be a major objective of any web or modem based reporting tool.

- *Integration of reporting function into software that does other things (billing, provision of HEDIS data, etc.).* Clinical data are often housed in information systems that support administrative functions such as billing or claims processing. Little work has been done to determine how these databases can be used to support surveillance activities. Demonstration funds could be used to fund partnerships between public health venues, providers, and software developers to integrate new features into existing software programs to automatically flag and capture information related to reportable cases.

- *Tapping existing data sources and resources.* Health information systems contain a wealth of potentially useful information; but, little has been done to explore the utility of existing

data sets, such as claims data, EMS logs, or pharmacy records, for use in surveillance activities. Other kinds of data sets, such as employer and school absentee data, may also be effective surveillance tools. The use of alternative data might require broadening the range of reportable information and the range of entities required to report. For example, dispensing of anti-tuberculosis medication is not generally reportable, yet this information could be the foundation of a much improved TB surveillance program. Tapping into new sources of data, however, will require legislative changes to expand the authority of public health entities to collect information from organizations other than providers (e.g. HMOs) and require these organizations to supply such data. Once new data sources are identified, it will be important to invest in model legislation and a program to move this legislation through the many jurisdictions that will need to consider it.

Demonstration studies to assess the utility of existing data sources for surveillance should be conducted by partnerships between the public health departments of regions, states, or large localities and organizations that house key data (HCFA, private health plans, pharmacy benefits managers, health systems, etc.). Researchers can systematically investigate multiple types of data sources, including Medicare, Medicaid, and private sector administrative and claims data, pharmacy records, emergency room and infection control data sources, and other potential sources of relevant information. This investment should also produce an analysis of the feasibility of using such data for surveillance purposes. The researchers must address issues such as confidentiality, proprietary rights, and quality of the data.

- *Centralization of reporting venues; public health handles the routing.* Currently, large health systems may need to report to multiple public health jurisdictions. One option for improving reporting is to provide grants to multi-state regions to centralize reporting venues and requirements such that providers would report electronically to only one centralized location using a standard format. The hub would automatically route the information to the appropriate health department. This approach may encourage more complete and timely reporting by large health systems or other providers that serve multiple jurisdictions.

  Lack of legal authority for cross-jurisdictional collection of surveillance information is a potential roadblock to technologies that involve centralizing reporting venues across states or even within states in some cases. Technological filters can be created that can deal with the different legal requirements across jurisdictions which can be an easier fix than changing the legal structure.

Any technology applications developed to improve the interface between the clinical care delivery system and public health venues must take into consideration the unevenness of technological capability across both provider organizations and local health departments and the lack of standards for information systems.

Level 1: *Investments to Improve Feedback to Provider Community*

Part of the reason the health care delivery system is not actively involved in surveillance is a disconnect between caregivers and the public health system. Providers are required by law to report cases of infectious disease, but rarely see the benefits from their efforts because the flow of

information is too often one way. Once a disease has been reported, providers are often asked to provide more clinical detail to case investigators. Providers need to feel that they are participating in a worthwhile effort both in terms of their own clinical practice and in terms of their contribution to the health of the public.

We recommend investments for CDC to support several communications efforts to improve feedback to providers. These include:

- *Periodic newsletter for the provider community.* The CDC would create the format and standard content for a quarterly provider newsletter. This newsletter could then be tailored by a specific region or state to include state or regional data summaries, regional "hot topics," and conference and meeting information. Such a newsletter, which could be widely distributed either on paper or electronically to physicians, hospitals, laboratories, pharmacies, schools of public health, and other institutions, would demonstrate the utility of provider-reported information and highlight the importance of surveillance activities. This newsletter could be modeled after the Oregon state health department's Communicable Disease (CD) Summary.

- *Develop new tools to enhance two-way communication between the provider and public health communities.* CDC would administer grants to partnerships of public health agencies and provider organizations to develop new approaches to communication. These might include websites that provide interactive data summaries where providers indicate their locality or specialty and customized reports could be automatically generated.

Level 2: *National Investment to Develop Facility-based Infection Control Professionals as Partners in Infectious Diseases Surveillance*

Experts consulted for this project widely agreed that infection control professionals are an extremely valuable but underutilized resource in the surveillance of infectious diseases. Experts believe that infection control programs have deteriorated and that staff have been diverted for other purposes, leaving them with little or no time to conduct traditional surveillance activities. Investments should be made to enhance the role of infection control professionals, with dedicated time and responsibilities for surveillance, in sentinel hospitals around the country. Matched funding would be made available to hospitals willing to participate in the program.

This demonstration program would select a sample of health care facilities stratified by size and location. These facilities would be paid to supplement their current surveillance activities with active case-finding of high priority conditions that are not reliably reported through the existing lab-based systems. These include conditions that are not legally reportable and therefore would fall through the cracks in the existing system or conditions where lab reports are not especially reliable or timely. A potential funded activity might include performing daily active case-finding in the ER, ambulatory care clinics, and nursing units for cases that meet specified criteria.

Research would need to be done at the outset to appropriately structure this program. Work done in Minnesota to nurture relationships with infection control nurses could provide a model.
Specific ideas to pursue include: tracking reasonably prevalent trends such as antimicrobial drug

resistance; running a series of short-term projects on specific issues such as an annual influenza project; or a study to track the spread of West Nile Virus along the east coast over the summer.

Level 3: *Investments to Increase the Perceived Importance of Surveillance Activities*

Another investment focuses on increasing the awareness of providers regarding surveillance issues and stressing the importance of this activity to the health care delivery system. We recommend investments in a national initiative aimed at elevating the importance of surveillance to the provider community. This initiative would be managed by CDC with the support of other federal agencies including HRSA. This office would be in charge of three major tasks:

- *Providing grants to partnerships between public health departments and educational institutions (schools of public health, medicine, nursing, allied health professionals, etc.) to develop and test model curricula to elevate awareness of, and training about, surveillance in educational programs.* Currently, most health care providers receive little structured instruction regarding infectious diseases surveillance. In order to strengthen the surveillance system as a whole, education of frontline health workers is critical. With a more in-depth understanding of and appreciation for surveillance, doctors, nurses, pharmacists, and public health workers could dramatically improve their participation in and support for surveillance activities. This grant program would be aimed at developing model curricula for a variety of training venues that could then be disseminated nationwide. The program office at CDC would be charged with evaluating the curricula developed and disseminating those curricula that appear to be effective.

- *Working with selected licensing agencies and certification boards to encourage them to require a very basic level of training in surveillance (initial requirements, CME requirements).* Licensing and certification are important mechanisms for ensuring that providers of health care are qualified and competent. By incorporating surveillance knowledge into requirements for training and CME, the provider community would receive a powerful message regarding the importance of surveillance.

Timing

The specific investments described above would be phased in over a five-year time period based on their level of importance. During the later years of the investments involving demonstration grants, the emphasis would be on dissemination of strategies that work. The interaction with licensing and certification boards would be a targeted two-year effort.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Demonstration grants to improve reporting					
– Award grants					
– Develop demonstrations					
– Evaluate outcome					
– Replicate					
Provider feedback effort					
– Develop templates					
– Disseminate materials; launch and maintain website					
Expanded role for hospital infection control professionals					
– Develop program and select participants					
– Implement program					
– Evaluate program					
Interface with licensing and certification boards					
Model curricula development					
– Award grants					
– Develop model curricula					
– Evaluate results					
Disseminate curricula					

B. Increase Public Support for and Engagement in Programs to Protect the Community from Infectious Disease Threats

Infectious diseases surveillance and control efforts are least visible when they are most successful. The public — and the public's institutions such as government and the press — usually become aware of infection control efforts when epidemics occur or impending disasters are narrowly averted. Since the activities needed to protect the public from infectious disease threats must be constantly maintained and the public health resources needed to respond to new threats must be ever ready, they need continuing support.

Although infectious diseases surveillance and control programs have been successful in the past, the view of many experts in the field is that they have come to be taken for granted and no longer receive the attention or funding they require to continue to be effective. A recent study by the Pew Charitable Trusts indicates that the general public has a very limited understanding of what public health is and what role public health officials play in protecting the population against disease. Typical parents of young children — and many grandparents — cannot remember the terrible effects of infections that were highly prevalent just a few generations ago, such as polio, whooping cough (pertussis), measles, and rubella. Few remember that tuberculosis was a leading

cause of death in the early part of the 20th century. These diseases have not been eradicated. They have only been contained. A breakdown in infection surveillance and control efforts can lead to their dramatic resurgence, as was illustrated when the Soviet Union's public health efforts disintegrated. It was also demonstrated in England when immunization rates for pertussis fell, as well as in the United States when resources for tuberculosis control were temporarily reduced. In each case, diseases thought to have been controlled quickly returned.

Strong social forces place surveillance activities at risk. The public is becoming increasingly concerned about privacy, and "surveillance" by the government is feared by many despite a strong public health track record in maintaining data security and confidentiality. Concerns about broadly-based communicable disease surveillance and control programs — universal childhood immunizations, as one prominent example — are increasingly being rejected by parents and others who mistakenly consider the risks of public health efforts to be greater than the risks of disease. Unfortunately, many clinicians similarly lack experience with previously common communicable diseases and are unable to provide compelling, first-hand testimony to their patients.

The public can play an important positive role in surveillance. At a minimum the cooperation of individuals is necessary to conduct case investigations so that contacts can be traced and action taken to prevent the spread of disease. Public awareness and involvement has at times played a critical role in detecting the extent of an outbreak. For example, the reach of the Jack-in-the-Box e. coli outbreak was determined to be much broader than originally thought when an individual in another state recognized the symptoms and contacted authorities because of media attention.

Thus, at this time, infectious diseases surveillance and control programs desperately need adequate financial support, strong political support, and widespread public understanding and support. Three groups are needed to gain that support: government leaders, community leaders, and influential members of the communications media. This segment of the investment plan is designed to give these groups continuing information about the status of emerging infections, the threats they pose if unchecked, the strategies needed to protect the public, and the successes and failures of those strategies.

The investment is limited in scope; it is not designed to educate the general public directly which would require extraordinary resources. The successful education of government and media leaders will likely enhance the understanding of the public as a collateral benefit.

Investment Objectives

The objective of the second component of priority two is to inform individuals within critical organizations about the value of infectious diseases surveillance and control efforts to:

- Create broader public constituencies;
- Recruit communities to play an active role in surveillance.

Investment Approach

This investment is intended to build a sophisticated understanding of surveillance needs, strategies, and techniques among key leaders to better engage communities in surveillance and control programs. This effort will supplement the current efforts by the DHHS, CDC, and many state and local health departments to educate the medical profession. For example, CDC's *Morbidity and Mortality Weekly Report* is widely distributed to public health professionals and has been praised for its ability to enlist the practicing clinical communities in important public health efforts. A similar effort is needed to enlist non-clinician leaders whose support is also critical.

Public education is a standard tool used by public health agencies. Because of the nature of this effort—enhancing public support for surveillance—however, these funds could be seen as supporting lobbying or some other inappropriate, self-serving promotion. While the funds are likely to be most effectively spent by public health officials who can best set priorities for education, identify emerging threats, and celebrate successes, we think that a foundation might be engaged to fund and manage this effort.

The specific goal of the two investments described below will be to develop and disseminate techniques and supporting materials:

- For use by state and local health departments, foundations, and other allies of public health;
- To be used to educate key constituencies about the value of surveillance:
  - Media,
  - Foundations and other funding agencies and organizations,
  - Providers and professional groups,
  - Community leaders;
  - Purchasers and payors;
  - Legislative, regulatory, and standards-setting bodies;
- To engage communities actively as partners and resources in surveillance.

Level 3: *Create Training Materials and Educational Programs*

Fund the development and dissemination of training materials and educational programs to improve the abilities of state and local health department representatives to work with their communities, legislators, county commissioners, and press contacts. Funding will support contracts, grants, and intramural educational program development and dissemination.

Specifically these funds would support the design, development, and deployment of training programs to improve the abilities of state and local health officials to engage communities in infectious diseases surveillance efforts and to communicate infectious diseases surveillance and control priorities to other government and media leaders.

Level 3: Develop and Disseminate Newsletter Templates

A separate funding stream will be devoted to the development and distribution of newsletters (paper or electronic) that can be used by state and local health departments to provide ongoing education to their key constituent groups. The newsletters will provide content that can be modified and supplemented by each public health agency to meet their local needs.

Timing

We expect a six month development period before the first courses could be offered to state and local health departments. Newsletters would begin to be disseminated within the first project year. Evaluation would begin in the second project year. Given the level of priority of these activities, we would expect them to begin in year 3.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Develop training materials and courses					
Offer courses to state and local health departments					
Develop, maintain, and disseminate educational newletters that state & local health departments can customize and distribute					
Evaluate quality and impact of programs					

3. Enhance Public and Private Laboratory Support for Infectious Diseases Surveillance

A. Better Coordinate Public and Private Laboratory Capacity to Support Infectious Diseases Surveillance

Surveillance for most reportable infectious diseases depends on reporting by clinical laboratories. The ability and willingness of laboratories to support public health surveillance are increasingly in jeopardy. This initiative is designed to assure that clinical laboratories, whose principal objective is to provide clinicians with information about the cause and treatment of infections affecting individuals, will continue to provide essential surveillance information to public health agencies.

Laboratory-based infectious diseases surveillance has offered important advantages in the past:

- Clinical laboratories have been able to provide standardized information about a large and representative portion of the nation's population. Cultures have been typically obtained from a large fraction of persons with potential infection who seek medical care throughout the nation, and clinical laboratories have used standardized techniques to study those specimens and commonly used nomenclatures to report their results.

- Laboratory-based surveillance has also been cost-effective. Surveillance data have been an inexpensive dividend of clinical testing. Information needed to treat a patient, the responsible microorganism's identity and its characteristics such as susceptibility to antimicrobial agents, for example, are often the information needed for infectious diseases surveillance, so additional testing has not usually been necessary.

- Clinical laboratories have reliable procedures to assure that the results of testing are reported to the requesting clinicians, and it has been easy to send duplicate data for reportable conditions to public health authorities.

These important advantages of laboratory-based surveillance are eroding, however. First, for some important conditions, it is no longer necessary for a clinician to know the cause of an infection to provide effective clinical care. Research has shown that a guidelines-directed treatment protocol based on clinical findings can produce just as good individual clinical outcomes as does a treatment plan that is based on culture results for some kinds of important infections. As all health care sectors focus increasingly on cost-effective care, we can anticipate that a smaller proportion of infected persons will have microbiology studies performed.

Second, advances in biotechnology are also changing the ways clinical laboratories work. Just as it is unnecessary for a clinician to know precisely which microorganism is causing infection in order to provide effective care, it is also increasingly possible for laboratories to provide a clinician with information about therapy (whether the protocol-derived antibiotic is likely to be effective, for example) without obtaining the information traditionally needed for public health surveillance. The divergence between microbiologic testing needed for clinical purposes and that needed for public health purposes is likely to widen in the future.

Third, reporting is also becoming more difficult for clinical laboratories. Intense competition has made it difficult for small, local laboratories to survive and has led to major consolidation of laboratory providers. Except for hospital-based laboratories for inpatient testing, a few national providers now dominate the commercial laboratory industry. Moreover, laboratory functions are being centralized so that one laboratory site may serve many states or even the entire nation. In the past, a local or regional laboratory could develop relatively simple systems to assure that reports were routinely sent to state or local health departments, but more complex and expensive systems are required for multi-state or national laboratories to report to the many jurisdictions that require the information. Jurisdictional differences in reporting requirements and formats add to the cost and complexity of reporting.

Economic competition has affected both public and commercial laboratories. State and local health departments are increasingly using commercial laboratories because they can be more cost-effective. Meanwhile, competition is also diminishing the willingness of some laboratories to assist with public health surveillance. Clinical service laboratories now depend on high-volume, highly automated procedures to remain competitive. Individual tests yield minuscule profits. As a result, additional work, such as reporting, is perceived to cut into already thin profit margins.

The changes in laboratory practice threaten to rupture a historical accord between clinical service laboratories and public health laboratories. Laboratories in both sectors are under economic pressures; as a result, competition threatens to replace cooperation. The roles of public health and commercial laboratories are blurred. Should public health laboratories provide clinical services in competition with private sector laboratories or should they only perform reference work that the private sector does not perform? Should commercial laboratories be expected to follow procedures that yield public health information when their clinician customers do not need that information? A volume-based commercial service laboratory sees any testing performed by the public sector as a threat, especially if the testing is subsidized by public funds. The public health sector is concerned that clinical specimens that are needed for epidemiologic assessment will no longer be available as commercial laboratories move to focused, minimalist, and clinically-driven testing protocols.

Investment Objectives

The objective of this component of priority three is to better coordinate public and private laboratory capacity to support infectious diseases surveillance to:

- Define and implement effective and efficient divisions of responsibilities and resources between private and public health laboratories;
- Ensure appropriate capacity exists within public health labs to carry out their responsibilities as defined above;
- Develop and then provide incentives to private laboratories to conduct the tests needed to support infectious diseases surveillance;
- Promote the use of techniques that meet both clinical and surveillance objectives;
- Increase ease, speed, and completeness of reporting by private service labs by moving more rapidly to electronic laboratory reporting on a regional or even national basis.

Investment Approach

This investment is intended to build a strong, durable, and mutually beneficial bridge between the public health surveillance sector and the clinical service laboratory sector. Three investment targets are proposed.

Level 1: *Support and Maintain a Laboratory Issues Advisory Panel*

We recommend that an investment be made to support and maintain a blue-ribbon advisory panel. This panel would be managed by the overarching structure that is overseeing the investment plan as a whole. The panel would be charged with clarifying the needs and roles of the public and private laboratory sectors, designing fair and effective systems to assure that both sectors can be effective and successful, and monitoring those systems into the future. This monitoring would assure that the relationships between the two sectors benefit from continued scientific progress and that financial pressures do not damage continued cooperation. Specifically, the investment will:

- Establish and maintain an ongoing, public-private, multidisciplinary task force at the national level that:
  - Represents critical scientific and business disciplines, e.g., epidemiologists, laboratory directors/executives, payors, microbiologists, economists, clinicians, and clinical and basic investigators;
  - Represents important stakeholder groups, e.g., national service laboratories, hospital laboratories, private reference laboratories, health plans, accrediting bodies, and federal and state agencies;
  - Develops a consensus list of critical laboratory data and techniques needed for effective surveillance and identifies appropriate sources (public vs. private labs);
  - Addresses what standard tests should be done and by whom in given situations;
  - Develops rational and fair incentives to private laboratories to provide the information and specimens needed to assure effective surveillance;
  - Develops standards for cross-state reporting, taking into account jurisdictional and legal issues;
  - Continuously monitors the changing utility of laboratory data in performing surveillance for important infectious diseases.

Funding would need to support 6 to 8 meetings per year (more in the early years, fewer later). The panel itself could consist of 15 to 20 members and would need staff support and periodic advice of technical and policy experts. This investment would also fund panel and staff participation in public meetings or conferences each year and the production and dissemination of findings, guidelines, and recommendations.

Proper levels of reimbursement to laboratories for services they provide and sources of reimbursement funds are likely to be contentious issues. We believe it is unlikely that commercial clinical laboratories will continue to perform the testing and reporting that are needed for surveillance but not for clinical care. Several alternative approaches exist to address these issues. Laboratories could be required by law or regulation to perform and report tests

without additional reimbursement. Compliance would be difficult to enforce, however, and the "unfunded mandates" would be shifted to other payors according to market forces. Alternatively, public health agencies could reimburse laboratories for the added services they perform, but this would require dedicated funding and regulatory and legislative action. The blue ribbon panel may be able to make recommendations about reimbursement issues, but it will not be able to mandate adoption of its recommendations.

Level 1: *Fund a Prototype Project; Deploy Nationally*

We recommend funding a prototype project to develop mechanisms to make it easier for laboratories to report to public health venues. This project would:

- Establish common reporting requirements across selected jurisdictions including:
  - List of reportable diseases,
  - Standards for laboratory data needed to confirm such cases,
  - Standards for data exchange built on national standards;
- Centralize reporting venues for electronic reporting: state, regions, or a centralized laboratory/control center take responsibility for routing to appropriate local jurisdictions;
- Develop electronic reporting capabilities at private and public health labs: labs send data to a publicly funded state/regional clearinghouse which receives and routes data;
- Evaluate and disseminate results.

This project would involve representatives of state and local health departments, large private laboratories, software vendors, major health care systems, Health Information and Surveillance Systems Board (HISSB), technology experts, and CDC. HISSB involvement would be especially critical to ensure that any technology developed conforms to new standards and builds upon existing efforts in this area. One of the roles of the Laboratory Issues Advisory Panel described above would be to oversee this effort to ensure that the prototype developed can be broadly applied.

Laboratory findings play a central, critical role in effective surveillance, but the rapid pace of scientific and economic pressures threatens the utility of laboratory reports. Some of the new systems, reporting relationships, model laws, and regulatory changes will need to be tested before they are implemented nationwide, however, so we propose that the development of systems be tested in a prototype project within a defined multi-state geographic area or among a network of laboratories that will lead the efforts in other regions/networks. This prototype project should not be considered a "demonstration project" upon which national funding is dependent. Instead, it is a laboratory where specific problems are resolved and then quickly deployed in elsewhere.

Timing

The blue ribbon panel should be up and running within the first year. The first regional program would span years one and two. Contingent on the results of an evaluation, national deployment would follow shortly thereafter.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Establish blue ribbon panel					
Implement prototype projects – Prototype development and evaluation – Nationwide deployment					

B. Speed Development and Dissemination of Lab Technology to Support Infectious Diseases Surveillance

Technological advances in microbiology are dramatically changing the ways that clinical and public health laboratories work. Expert panelists and key informants noted two issues related to this technological change that need to be addressed to ensure that public health laboratories are part of this technology revolution. First, laboratory technology development to support public health activities needs to remain on par with development supporting clinical activities. Second, public health laboratories need to have access to the most advanced technologies available.

Most research aimed at developing new laboratory technologies goes to developing technology for clinical, not public health, uses because of the larger size of the clinical testing market. Until recently, clinical and public health microbiologists used similar laboratory techniques to meet their different objectives. Procedures that gave clinicians the information they needed for diagnosis and treatment decisions provided as a dividend the specimens and information needed to conduct infectious diseases surveillance. Recently, however, there has been an increasing divergence in the techniques used by clinical vs. public health venues and the information obtained. Current research supporting clinical laboratories is influenced by incentives to develop quicker and cheaper tests. This new clinical technology is resulting in less information and fewer specimens to support surveillance of infectious diseases. We can no longer be confident that discoveries in clinical and public health microbiology laboratory techniques will reinforce one another. Accordingly, strong public health laboratories that can support the recognition and investigation of new and emerging infectious microorganisms will require targeted research to develop new techniques.

Research and development are only part of the problem facing public health laboratories. Our research indicates that many public health laboratories have not adopted the advanced technologies that are already in existence. Recombinant technology, sequence-based molecular epidemiology, immunologic identification of pathogens, and techniques for the rapid

identification of antimicrobial resistance patterns are critical areas of advancement in which many public health labs have not kept pace. Part of this is a knowledge issue—the pace of technological change is rapid and it is difficult for each public health laboratory director to keep up to date. It is also a funding issue—many new technologies are expensive to implement, requiring new equipment, new reagents, and staff training.

Investment Objectives

The objective of this component of priority 3 is to speed the development and dissemination of lab technology to support infectious diseases surveillance by:

- Producing a research environment where public health microbiology research can compete:
  - with other federal funding priorities,
  - with private-sector research for the talents of innovative, productive investigators;
- Providing resources to conduct research;
- Assuring that research is transferred to practice effectively and efficiently.

Investment Approach

This investment is designed to develop and sustain a significant program in public health microbiology research and development, a program that will use state-of-the-art concepts and techniques that are currently revolutionizing clinical medicine. It is also designed to ensure technological developments are quickly disseminated to and adopted by public health laboratories. The investment will be targeted to four activities.

Level 2: *Create a National Laboratory Technology Assessment Committee*

We recommend the creation of a national laboratory technology assessment committee to:

- Assess current technology gaps and recommend approaches for closing gaps;
- Assess new technologies and when applicable develop deployment recommendations;
- Help states/localities make the case for necessary funding;
- Allocate a pool of money that would be targeted at "raising the bar" for public health lab technological capabilities.

This national committee would feed information to regional subcommittees that would allow the direct involvement of state public health laboratory directors in the technology assessment process. Input from this committee would also help guide and structure the additional recommended activities described below. The national committee would meet quarterly. It

would be composed of approximately 20 individuals representing public health laboratories, public health departments, CDC, and the private sector. It would require staff support from the body overseeing this investment plan as a whole.

The Laboratory Response Network (LRN) is a possible model for the public sector development and deployment of technology. In the model, federal laboratories develop technology that is funded for evaluation in advanced public health laboratories. When proven efficacious, it is deployed throughout the system. The CDC PulseNet™ system is another model.

Level 2: *Fund Extramural Development Efforts*

The majority of funds for research and development should be awarded in extramural grants to develop new laboratory technologies to support the surveillance of infectious diseases. Much of this effort could be devoted to the application of existing knowledge to meet public health needs. These grants would be awarded based on a set of research priorities determined by the national technology assessment committee discussed above. These grants would help to foster partnerships among private R&D enterprises, public health labs, and universities to speed development and approval of new technologies of public health import. Other incentives could be developed to spur technology development in the private sector such as licensing deals.

CDC should develop a program office to solicit, award, and manage these research grants. CDC already awards grants, and it has a substantial contracts program. Its grants and contracts have typically been designed to develop and deploy public health programs. It has in some instances supported research and development. CDC will need to enhance systems and expertise in coordinating this type of research. To build upon its existing competency in grants and contracts management, some of the funding should be used to support the microbiology research and development grants office, which would manage peer review of grant proposals.

Research and development has not been a significant CDC mission. The National Institutes of Health (NIH) has historically managed research and development grants for medicine and the National Institutes for Science and Technology (NIST) has managed research for technology development. Expanding CDC's mission to support this type of effort is attractive because CDC has the program expertise to set appropriate research objectives. This may be opposed by both CDC, NIH, and/or NIST and it could lead to inefficient competition and duplication. As an alternative approach, NIH or NIST could be assigned the task of developing this research program although these organizations do not necessarily have the public health expertise equivalent to CDC's. As a third alternative, CDC could collaborate with one or both of these other organizations in managing this activity, taking advantage of CDC's program direction, NIH's expertise in managing basic research, and NIST’s experience in working with the private sector.

Level 2: *Fund Intramural Research*

CDC has traditionally been a site where innovative public health research is conducted, and it should remain so. Incremental research funds should be directed to intramural research and

development at CDC. The review process for such funding should include a peer component (NIH model) to ensure that local and state priorities are achieved.

Timing

This program would begin in year 2 of the investment plan. The first six months to a year of the program would be devoted to developing the grant-making office and organizing the technology assessment committee. Grants would be funded beginning early in year 3. Evaluation would be conducted concurrently to grant-making activity.

Timeline

Activity	Year 1	Year 2	Year 3	Year 4	Year 5
Organize and staff grant-making office; recruit extramural expert advisors and committee members					
Solicit research proposals					
Award grants					
Fund Awards					
Recruit and deploy intramural CDC basic research activity					
Convene technology assessment committee					
Evaluate results					

AREAS FOR ADDITIONAL RESEARCH

There were several areas addressed earlier in this investment plan where the expert panel saw the need for additional research before pursuing specific investments. Oversight for this research would be the responsibility of the overarching management structure for the investment plan as a whole. Research questions raised by the panel include:

- Is there a need for more epidemiologists coming out of training programs or:
  - Is there simply a problem matching them with open positions?
  - Is there a lack of funding for positions (i.e. health departments need individuals trained in epidemiology but do not have the funding to create the positions)?
  - Are the salaries and benefits available in public health departments insufficient to attract high quality people to these positions?

- Would redistribution of resources (staff or technology) help to alleviate perceived shortages?

- What tools have already been developed to automate epidemiological analysis of surveillance data and/or support decision-making?

- How does legal authority impact how surveillance systems operate and what limitations does this pose in efforts to make surveillance activities less fragmented?

- What portion of funding for surveillance comes from the federal government?

- What strategies have been successful in building local capacity for surveillance?

- What would make clinicians report? What strategies have been successful?

CONCLUSION

Table 1 summarizes all of our proposed investments. We recommend that this investment plan be evaluated in its entirety against the existing and planned activities of the CDC and other federal agencies with respect to surveillance. Given the perceived threat of emerging infections, bioterrorism, antimicrobial resistance, and other trends in infectious diseases, program development is progressing at a rapid pace. We did not attempt to assess the full range of current federal, state, or local efforts to improve infectious diseases surveillance. Instead, this project focused on assessing the current gaps in the system of infectious diseases surveillance as perceived by experts in the field and as observed in our site visits.

Even though the gaps addressed in this investment plan were mostly identified through interviews and site visits with individuals and venues outside of the federal government, not surprisingly the gaps appear to be fairly consistent with gaps as perceived by key decision-makers in the federal government; therefore our proposals have some degree of overlap with current federal priorities. Implementation of this investment plan, however, would require a substantial increase in funding relative to current levels. Increases would include federal investment in human capital to support surveillance at the state and local level through efforts focused on staffing levels, training and skill development, technological support, provider and public education, role definition, etc. These efforts would occur along side current efforts to increase technological capacity. Technology has tremendous potential to improve infectious diseases surveillance and free up existing staff resources to analyze data, investigate outbreaks, and implement prevention measures. However, many localities do not have people to perform even the most basic functions. Additionally, technological improvements to surveillance capacity will require targeted investments to ensure that staff capacity, training, and technical support are in place to allow new systems to operate effectively and change the way surveillance is conducted in this country.

The above points highlight the importance of the oversight and evaluation component of this investment plan. Oversight and coordination of the full range of surveillance related activities is critical to ensure that money is used wisely. These efforts must ensure that the system becomes

less rather than more fragmented over time and must support a movement from the paradigm of medical care and public health as completely separate toward one that considers them as parts of an integrated whole. Evaluation efforts will be critical to objectively assess the ability of various approaches to have a measurable impact on the performance of our national "system" for infectious diseases surveillance. Specifically this investment plan should be evaluated in terms of its success in:

- Improving local preparedness to identify, assess, and respond to infectious disease threats;
- Improving analytic capacity to detect outbreaks and changes in the epidemiology of infection and to plan and evaluate prevention and control strategies;
- Engaging the clinical delivery system, laboratories, and communities as partners in protecting the health of the public against infectious disease threats;
- Streamlining and simplifying the current "systems" for infectious diseases surveillance;
- Ensuring the technology (laboratory and information technology) supporting infectious diseases surveillance is on the cutting edge.

Table 1
Summary of Investments

Priority	Priority Level	Investment Approach
Manage investments, evaluate results, and coordinate with other surveillance activities	1	• Creation (or designation) and staffing of an appropriate area within CDC to perform this role
1. Improve state and local preparedness to identify and respond to infectious disease threats.		
a. Improve local capacity to conduct surveillance of infectious diseases	1	• Grant/technical assistance program to state and local partnerships to increase staffing and skill levels
b. Increase staff and technological capacity for epidemiological analysis at the state and (large) local level	2 2 3 3	• Direct program funding to increase staff • Grants to develop prototype tools to support analysis of surveillance data • Scholarships and field placements • Model curricula development
2. Engage the health care delivery system and the public as partners in infectious diseases surveillance		
a. Better engage the health care delivery system in infectious diseases surveillance	1 1 2 3	• Demonstration projects to make reporting easier • Outreach and feedback to better engage the delivery system • Expanded role for facility-based infection control professionals • Efforts to increase the perceived importance of surveillance activities
b. Increase public support for and engagement in programs to protect the community from infectious disease threats	3 3	• Training materials and educational programs • Newsletter templates
3. Enhance public and private laboratory support for infectious diseases surveillance.		
a. Better coordinate public and private laboratory capacity to support infectious diseases surveillance	1 1	• Ongoing multidisciplinary, public-private task force to address this issue • Prototype projects to rationalize laboratory reporting and implement electronic reporting
b. Speed development and dissemination of lab technology to support infectious diseases surveillance	2 2 2	• National laboratory technology assessment committee to prioritize research areas and assess new technologies for dissemination • Extramural research and development grant program • Intramural research and development grant program