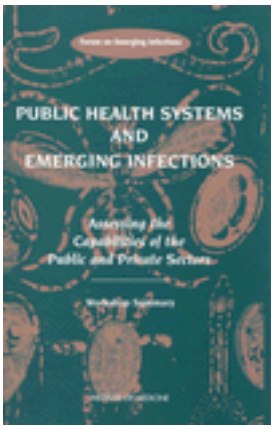

Public Health Systems and Emerging Infections: Assessing the Capabilities of the Public and Private Sectors: Workshop Summary

Jonathan R. Davis and Joshua Lederberg, Editors; Based on a Workshop of the Forum on Emerging Infections, Division of Health Sciences Policy

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Workshop Summary

Jonathan R. Davis and Joshua Lederberg, *Editors*

Based on a Workshop of the
Forum on Emerging Infections

Division of Health Sciences Policy

INSTITUTE OF MEDICINE

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This report is based on the proceedings of a workshop that was sponsored by the Forum on Emerging Infections. It is prepared in the form of a workshop summary by and in the name of the editors with the assistance of staff and consultants, as an individually authored document. Sections of the workshop summary not specifically attributed to an individual reflect the views of the editors and not those of the Forum on Emerging Infections. The content of those sections is based on the presentations and the discussions that took place during the workshop.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logotype by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

COVER: The background for the cover of this workshop summary is a photograph of a batik designed and printed specifically for the Malaysian Society of Parasitology and Tropical Medicine. The print contains drawings of various parasites and insects; it is used with the kind permission of the Society.

"Knowing is not enough; we must apply.
Willing is not enough; we must do.
—Goethe

INSTITUTE OF MEDICINE

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REVIEWERS

All presenters at the workshop have reviewed and approved their respective sections of this report for accuracy. In addition, this workshop summary has been reviewed in draft form by independent reviewers chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the Institute of Medicine (IOM) in making the published workshop summary as sound as possible and to ensure that the workshop summary meets institutional standards. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

The Forum and IOM thank the following individuals for their participation in the review process:

Kenneth Bart, San Diego State University Graduate School of Public Health
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David Smith, Texas Tech University Health Sciences Center

Although the independent reviewers have provided many constructive comments and suggestions, responsibility for the final content of this workshop summary rests solely with the editors.

Preface

The Forum on Emerging Infections was created in 1996 in response to a request from the Centers for Disease Control and Prevention and the National Institutes of Health. The goal of the Forum is to provide structured opportunities for representatives from academia, industry, professional and interest groups, and government* to examine and discuss scientific and policy issues that are of shared interest and that are specifically related to research and prevention, detection, and management of emerging infectious diseases. In accomplishing this task, the Forum provides the opportunity to foster the exchange of information and ideas, identify areas in need of greater attention, clarify policy issues by enhancing knowledge and identifying points of agreement, and inform decision makers about science and policy issues. The Forum seeks to illuminate issues rather than resolve them directly, hence it does not provide advice or recommendations on any specific policy initiative pending before any agency or organization. Its strengths are the diversity of its membership and the commitment of individual members expressed throughout the activities of the Forum.

A critical part of the work of the Forum is a series of workshops. The first of these, held in February 1997, addressed the theme of public- and private-sector collaboration (IOM, 1997b). The second workshop took place in July 1997 and explored aspects of antimicrobial resistance (IOM, 1998). The third workshop (IOM, 2000), examined the implications of managed care systems and

*Representatives of federal agencies serve in an *ex officio* capacity. An *ex officio* member of a group is one who is a member automatically by virtue of holding a particular office or membership in another body.

the ability to address emerging infectious diseases in the age of managed care. The fourth workshop, which this document summarizes, examined the core capacities of the public and private health sectors in emerging infectious disease surveillance and response. The fifth workshop, October 1999, examined the international aspects of emerging infections. The summary of that workshop is in production. The topic of zoonotic diseases will be the focus for the Forum's sixth workshop, to be held in June 2000.

ABOUT THE WORKSHOP

The changing face of health care poses new challenges for the detection, treatment, and prevention of infectious diseases. Historically, local public health departments, hospitals, and clinics have been at the forefront of infectious disease outbreak detection and treatment. However, the health care system has changed, and managed care organizations and privatized public health laboratories (often privatized for political reasons) continue to grow in response to the needs of the communities they serve. Yet, simultaneously, many of the system's abilities to perform its functions of public health laboratories and epidemiological services may be eroding. Along with that erosion, local public health systems may have a diminished capacity to detect and respond to an emerging infectious disease.

In an effort to increase our knowledge and understanding of the role of the private and public health sectors in emerging infectious disease surveillance and response, this workshop, entitled *Public Health Systems: Assessing Capacities to Respond to Emerging Infections,* explored how the privatization of public health laboratories and the modernization of public health care may effect infectious disease surveillance and outbreak detection. A central theme running throughout the workshop was the problematical capacity of public health systems at the state and local levels to detect and respond to an infectious disease outbreak. The workshop served to open a dialogue on public health systems to identify and discuss issues of mutual concern among representatives from the affected parties and groups. These issues were broken down into the following four thematic areas, which addressed various components of the public health system:

1. epidemiological investigation;
2. surveillance;
3. communication, coordination, and education and outreach; and
4. strategic planning, resource allocation, and economic support.

Representatives from the public health community, hospitals, government agencies, pharmaceutical companies, and academia were invited to give panel presentations moderated by Forum members. Each panelist was asked to highlight important issues, suggest possible practical solutions, and indicate impedi-

ments that must be overcome to improve infectious disease surveillance and response, communication and coordination, and education and outreach.

ORGANIZATION OF THE WORKSHOP SUMMARY

This report of the Forum-sponsored workshop is prepared in the form of a workshop summary by and in the name of the editors with the assistance of staff and consultants, as an individually authored document. Sections of the workshop summary not specifically attributed to an individual reflect the views of the editors and not those of the Forum on Emerging Infections, nor its sponsors. The content of those sections is based on the presentations that took place during the workshop.

The workshop summary is organized as a topic-by-topic description of the presentations and discussions that occurred during the workshop. Its purpose is to present lessons from relevant experience, delineate a range of pivotal issues and their respective problems, and put forth some potential responses as described by the workshop participants. The Summary and Assessement chapter discusses the core messages that emerged from the speaker presentations and ensuing discussions. Chapter 1 is an introduction to the topic and overview of the main issues confronting public health systems. Chapters 2 to 5 begin with opening statements that provide context and background information by the editors, followed by descriptions of the presentations that were made by the invited participants. Appendix A is a glossary and list of acronyms useful for the topics. Appendix B presents the workshop agenda. A summary of the GAO report on *Emerging Infectious Diseases* is found in Appendix C. Forum members and staff biographies are presented in Appendix D.

Although this workshop summary provides an account of the individual presentations, it also reflects a very important aspect of the Forum philosophy. The workshop functions as a dialogue among representatives from different sectors and presents their beliefs on which areas may merit further attention. However, the reader should be aware that the material presented here expresses the views and opinions of those participating in the workshop and not the deliberations of a formally constituted Institute of Medicine study committee. These proceedings summarize only what participants stated in the workshop and are not intended to be an exhaustive exploration of the subject matter.

ACKNOWLEDGMENTS

The Forum and the Institute of Medicine wish to express their warmest appreciation to the individuals and organizations who gave valuable time to provide information and advice to the Forum through participation in the workshop. Each of the following contributed greatly: Scott Becker, Association of Public Health Laboratories (APHL); Cheryl Beversdorf, Association of State and Territorial Health Officials (ASTHO); Eric Blank, APHL; Judy Buckalew, Office of Senator Lauch Faircloth; Jack Chow, Senate Appropriations Committee, Labor, Health, and Human Services Subcommittee; Donna Crane, American Public Health Association; Ellen Gadbois, Office of Senator Edward Kennedy; Mary Gilchrist, University of Iowa Hygienic Laboratory; JoAnne Glisson, American Clinical Laboratory Association; James Hadler, Connecticut Department of Health; Peggy Hamburg, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services; Tracey Hooker, National Conference of State Legislators; Eileen Koski, Quest Diagnostics; Marsha Lillie-Blanton, U.S. General Accounting Office; Laurence McCarthy, MRL Pharmaceuticals, Inc.; Joe McDade, Centers for Disease Control and Prevention; Linda Miller, SmithKline, Beecham; Ellen Morrison, U.S. Food and Drug Administration; Steve Ostroff, National Center for Infectious Diseases (NCID), CDC; Patricia Quinlisk, Iowa Department of Health, Council of State and Territorial Epidemiologists; James Pearson, Division of Consolidated Laboratory Services, Commonwealth of Virginia; Gianfranco Pezzino, Kansas Department of Health and Environment; Robert Pinner, NCID/CDC; William L. Roper, Dean, School of Public Health, University of North Carolina; Robert Rubin, The Lewin Group; Ted Shortliffe, Stanford University; Catherine Slemp, West Virginia Department of Health; Larry Strausbaugh, Portland VA Medical Center; Bala Swaminathan, NCID/CDC; Fred Edgar Thompson, Jr., Mississippi Department of Health, ASTHO; Helene Toiv, GAO; and Kathleen Young, Alliance for the Prudent Use of Antibiotics.

The Forum is indebted to the IOM staff who contributed during the course of the workshop and the production of this workshop summary. On behalf of the Forum, I gratefully acknowledge the efforts led by Jonathan Davis, study director for the Forum and co-editor of this report, who dedicated much effort and time to developing this workshop's agenda and for his thoughtful and insightful approach and skill in translating the workshop proceedings and discussion into this workshop summary. I would also like to thank the following IOM staff for their valuable contributions to this activity: Vivian Nolan assisted with the development of the workshop agenda, provided detailed support to facilitate the development of the workshop summary, and assisted with editing various sections of the workshop summary in response to the review process; Nicole Amado assisted in developing the Glossary and Acronyms list and provided comprehensive administrative support; and Sarah Pitluck, Alden Chang, Thelma

Cox, and Hallie Wilfert provided expert support at various developmental stages of the workshop summary. Other IOM staff also provided invaluable help: Sue Barron, Clyde Behney, Claudia Carl, Michael Edington, Carlos Gabriel, and Andrew Pope. Consultant and technical writer, Kathi Hanna, contributed significantly to writing many sections of the workshop summary. The extensive commentary and suggestions made by the copy editor, Michael Hayes, are gratefully acknowledged.

Finally, the Forum also thanks its sponsors that supported this activity. Financial support for this project was provided by the U.S. Department of Health and Human Services' National Institutes of Health, Centers for Disease Control and Prevention, and Food and Drug Administration; U.S. Department of State, Bureau of Oceans and International Environmental and Scientific Affairs; U.S. Department of Veterans Affairs; Abbott Laboratories; American Society for Microbiology; Applied Microbiology, Inc.; Bristol-Myers Squibb Company; Burroughs Wellcome Fund; Eli Lilly & Company; Glaxo Wellcome; F. Hoffmann-La Roche; Merck Co., Inc.; Pfizer; SmithKline Beecham; and Wyeth-Ayerst Laboratories.

Joshua Lederberg
Chair

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Summary and Assessment

Joshua Lederberg, Ph.D.
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Emerging infections are clinically distinct conditions whose incidence in humans has been shown to be increasing (IOM, 1992). These diseases continue to disrupt the health care system, and successful detection and treatment of these diseases is becoming increasingly complicated. The public health system also is continually challenged by unexpected disease outbreaks, whether an influenza epidemic or an act of bioterrorism. To be prepared and responsive to these infections and outbreaks, the public health infrastructure requires attention and resources.

Periodic infectious disease outbreaks serve to remind the public of the importance of the public health system. That outbreaks and epidemics of infectious diseases have been successfully prevented or controlled leads to the common misconception that the public health system is more than sufficient. Such misconceptions, however, belie the true risks to public health, and reinforce the public's expectations in the face of increasingly complex emerging infections and the changing health care environment.

Disease investigations are now more complex in nature than they were in the past because of a variety of new pathogens and risk factors, outbreaks, and bioterrorist activities that cross state and national boundaries—often raising political and economic concerns. The ability to quickly recognize and respond to widely dispersed disease outbreaks is a challenge to the public health system, particularly in an era of increasing global population mobility and the wide distribution of centrally produced foods.

To further complicate matters, emerging infectious diseases are competing with other types of diseases and with other health care priorities. The practice of public health is moving away from the traditional focus on communicable disease control and into new arenas, such as chronic disease and injury prevention. Simultaneously, public health programs have been dramatically underfunded, with less than 1 percent of the $1 trillion investment allocated to health care going to support public health functions (Margaret Hamburg, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, personal communication, November 1998). In the mid 1980s to early 1990s, the relative percentage was actually declining, despite a renewed attention to and appreciation of the critical role of public health, and the expanding demands on public health systems. For example, in 1992 the United States spent only approximately $74.5 million for all infectious disease surveillance through the public health system (Michael Osterholm, state epidemiologist and chief, Minnesota Department of Health, personal communication, November 1998).

Another challenge facing the public health system is its fragmentation and dependency on categorical funding systems at the national, state, and local levels. Dependence on the one-time investments that states and localities choose to make to support surveillance activities and dependence on the leadership that may emerge by chance in the state or local public health department compromise the sustained efforts needed to support the public health system. A renewed commitment to a national approach to infectious disease surveillance is needed both to support new requests for funding and to sustain the full range of activities related to infectious diseases that confront public health today.

To help inform the debate about the capability of the public health system to respond to and control emerging infections, the Forum on Emerging Infections convened a workshop—the subject of this workshop summary—to identify, clarify, and solidify some of the current and potential best practices in the public health arena to combat the threat of emerging infectious diseases. The workshop focused on four major areas of importance to public health systems that both shape and are shaped by the nature of emerging infections: (1) epidemiological investigations, (2) disease surveillance, (3) communication, coordination, and education and outreach, and (4) strategic planning, resource allocation, and economic support (see Appendix B, Workshop Agenda).

At the workshop, participants described the components of the current system at the national, state, and local levels. In the ensuing discussions, participants debated many of the challenges that must be overcome and identified possible opportunities for addressing the obstacles. These discussions emphasized three cross-sectoral thematic areas in which carefully placed investments could make a positive contribution toward improving the capability of public health systems to respond to emerging infections: (1) integration of public health systems, (2) investment in human capital, and (3) improved collaborations between the private and public sectors.

This summary highlights the workshop presentations and analysis of the discussions. The first section, Assessing the Capability, is a summary of the presentations and discussions surrounding the four major topics of the workshop. The subsequent section, Strengthening the Capability, is an analysis of the three thematic areas and the challenges and opportunities that the public health system faces in each. The final section presents some concluding remarks. The views and opinions discussed in this workshop summary, as well as the challenges and opportunities, do not necessarily represent the views of the Forum on Emerging Infections or the Institute of Medicine.

ASSESSING THE CAPABILITY

Epidemiological Investigations

Because emerging infections continue to disrupt the health care system and their detection and treatment are becoming increasingly complicated, it is essential that public health agencies frequently and methodically make every effort to collect, assemble, analyze, and make available health information about the community. This not only entails the provision of health status statistics and community health needs but also requires epidemiological studies of health problems. Diagnosis and investigation of health hazards within a community can be performed by health departments at the federal, state, and local levels if they have the appropriate levels of resources, adequately trained personnel, and established systems of reporting and communication. Although each sector faces some common and unique challenges, each component may also require coordination at several levels, from the local to the state to the federal level.

Federal resources, through the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Food Safety and Inspection Service (FSIS), are available to assist in infectious disease investigations, but they can do so only if state and local public health agencies have the infrastructures in place to detect and report unusual disease occurrences. Investigators at the federal level, largely through CDC, have better investigational tools, such as computerized databases, computational technology, and electronic mail, which has allowed individuals and federal agencies to recognize and report incidents that might not otherwise have been detected. An additional important service of the CDC is assistance with outbreak notification to other federal agencies and jurisdictions. Finally, the CDC can assist with the implementation of control measures.

Two other federal agencies also play a vital role in many foodborne illness-related outbreak investigations because of their regulatory mandates. The U.S. Food and Drug Administration, a sister agency to CDC in the Department of Health and Human Services, has regulatory oversight over food products except meat, poultry, and egg products, which is the purview of the Food Safety and

Inspection Service, the public health agency of the Department of Agriculture (USDA).

In recent years, FDA has tried to improve its coordination of multi-state outbreaks with CDC and other federal agencies. Because foodborne outbreaks frequently involve low-level, sporadic contamination of widely distributed food, often food from other countries, FDA must interact with multiple federal agencies and jurisdictions. The FDA Division of Federal-State Relations aims to conduct outreach and coordinate such efforts. In 1997, FSIS' Office of Public Health and Science created the Epidemiology and Risk Assessment Division that includes eight field epidemiologists who assist states, local jurisdictions, and CDC with trace-back efforts during outbreaks where FSIS-regulated products have been implicated. Additionally, at the level of the Assistant Secretary for Food Safety of USDA, the Foodborne Emergency Response and Rapid Evaluation Team (FERRET) has been created to facilitate a prompt, effective, and coordinated response to food emergencies by the many USDA agencies.

State health departments are often at the front line of outbreak investigations and receive news about an illness from many sources, such as the medical care system, the public, the disease surveillance systems of other public health institutions, or the news media. Once the cause of an outbreak is determined, control and prevention measures must be implemented. These may include educating the population at risk, providing direct medical intervention (e.g., prophylaxis with antibiotics), or ensuring withdrawal of a product from the market. Documentation that details the process of the investigation, the findings, and the recommendations is often required at the state level.

In general, epidemiological investigations and surveillance efforts at the state level are challenged by a variety of factors, such as changes in the health care system. In addition, many states are still using paper-based disease reporting systems. A number of states do not have a state epidemiologist, and the responsibility of daily disease surveillance is often sporadic and inadequate. Better computational resources could improve the system and accelerate disease reporting.

Local health departments face the strains of an insufficient infrastructure. At a bare minimum, local health officials need basic investigational skills, such as how to design appropriate questionnaires and improve interviewing techniques. They also need to learn proper methods for the collection of environmental and clinical specimens, as well as advanced computer and communications skills, including skills that permit them to better interact with the media. Importantly, they need to extend these skills beyond food-borne outbreak investigations, which are the most common types of investigations at the local level, to investigations of respiratory illnesses in school systems, occupational exposures, and nosocomial infections. Local public health departments, however, are often plagued with a high rate of staff turnover, poor pay, intermittent calls for indi-

viduals with unique skills, and inadequate financial support, thus making maintenance and continuity of skills difficult and training essential.

Historically, clinicians have played a central role in outbreak investigations and disease surveillance. Long before the causative agents of infectious diseases were known, the observations of medical practitioners served to alert the community to unusual medical occurrences. Even after the etiologies of infectious diseases were unraveled and laboratory tests made available, clinicians still played an essential role in providing patients for study and assisting in some epidemiological investigations. Today, however, many physicians often are not sure when or where to report suspicious cases of infection, are unaware of the need to collect and forward clinical specimens for laboratory analysis, and may not be educated regarding the criteria used to launch a public health investigation. Moreover, there is often a lack of communication among public health agencies and community physicians.

Academic institutions must assume a primary role in keeping practicing health professionals informed about the new knowledge, practices, and technologies that can be used to respond to emerging infections. Academic health centers must capitalize on new technologies in continuing education, distance learning, and executive training that make use of the Internet, wide-area computer networks, and satellite-based communications capabilities. To be effective, these activities must be conducted in close partnership with national, state, and local public health organizations.

Cultural and conceptual gaps exist across the various disciplines and levels that are involved in integrated and effective public health research and practice. The key elements that comprise an integrated public health system include solid capabilities in basic laboratory, epidemiological, clinical, behavioral, and health care services, and policy research, as well as effective education and public outreach. The gaps among these elements include those that have historically existed between academic public health institutions and academic medical institutions and between academic public health institutions and the larger health care sector. The historical disconnect that exists between academic public health and the larger health care sector, particularly as it pertains to private health care delivery systems and diagnostic laboratories, must be repaired to maintain adequate responses to emerging diseases.

Surveillance

Surveillance is an early-warning system for diseases and must be the first link in the chain of public health action, as it is an essential element for any disease control or eradication effort. It is a daily responsibility that at present is somewhat sporadic and mostly inadequate in its current capability to anticipate and detect early emerging disease trends in the United States. Surveillance is a science and a tool, and is typically foreign to the traditional academic medical

curriculum in the United States. Although a tremendous amount of surveillance is accomplished, much of it is disease-specific, resulting in disjointed programs and unsustainable systems supported by categorical funding.

Traditional public health surveillance involves concurrent epidemiological investigations, laboratory analysis, and health care delivery as well as the following activities: (1) identification of unusual clusters of disease and their geographic and demographic spread, (2) estimation of the magnitude of an outbreak and a description of its natural history, (3) determination of the factors responsible for the emergence of a disease, (4) laboratory and epidemiological research, and (5) successful specific intervention efforts. To accomplish this, public health surveillance relies on the ongoing and systematic collection, analysis, and interpretation of data that are reported to a central agency in a timely manner.

Public health surveillance systems can vary in their objectives, work scopes, and methods, and in terms of whether they are either privately or publicly supported or operated. They can range from complex international networks to small, community-based programs. Monitoring measures within these systems are either passive or active. The characteristics that are vital to one system may be less important to another. Moreover, efforts to improve the quality of one system may impair the functioning of another system.

A public health surveillance network needs to have a balance of characteristics from each system—from the national, state, and local levels and from both the public and the private sectors. One area of focus that can achieve that balance should be population-based strategies, which provide the foundation upon which disease incidence and prevalence are enumerated and from which all subsequent response activities originate. Population-based surveillance provides the means to differentiate between anecdotal or temporal reports of cases and actual outbreaks of infection. An emphasis on population-based disease surveillance also necessitates the development of a set of standards for epidemiological investigations, laboratory analyses, case reporting across geographical and jurisdictional boundaries, and personnel qualifications.

The public health capacity for population-based disease surveillance, however, is highly variable among states and varies even more widely among county and local health departments. Disease surveillance systems at the national, state, and local levels have developed independently in response to various health crises and needs, recent legislation, and available resources. Accordingly, there is a need to integrate existing public health surveillance systems. For example, 50 to 60 different infectious disease surveillance systems exist nationwide. The regionalization of surveillance systems and laboratory capacity is one means of integration, but this issue requires further discussion.

The Emerging Infection Program (EIP) network, sponsored by CDC, is one program that emphasizes the importance of population-based disease surveillance and the dimensions and texture of surveillance information. The EIP network has formed the basis of a surveillance system that needs continued and

increased support. This large, national effort has helped public health laboratories to contend with the challenges of multiple jurisdictions and their reporting requirements. This type of a network between the private and public sectors, however, requires a certain level of data standardization, a goal that has not been fully met.

A thorough review of the public health infrastructure is warranted to create a new, comprehensive national plan to develop and apply established standards for the public health infrastructure (laboratory, epidemiological, communications, and personnel standards) within and across the public and private sectors. A national commitment is therefore necessary to maintain a network and its readiness through standardization and proficiency testing. A national surveillance plan should take into account the diverse surveillance uses of data, approaches, and emphases at different levels of government, as well as anticipated capacity needs and scope of testing. Routine collection of surveillance data will be an invaluable resource in retrospective analyses for surveillance purposes. In addition, the results obtained from evaluations of these disease surveillance data must be freely shared among federal, state, and local agencies, as well as between the public and the private sectors, for infectious disease surveillance to be effective. Withholding of surveillance data on disease prevalence and incidence for marketing and economic reasons can be detrimental to disease surveillance activities.

Improving the infectious disease surveillance infrastructure requires coordination and collaboration, not the fragmentation and duplication of laboratory services. A lack of standardization of the data elements to be reported can impair the ability of the private sector to report back to the state epidemiology officer and challenges the reporting systems of the state health laboratory. In addition, disjointed programs as a result of categorical funding do not allow some states to be able to monitor disease trends. For example, many states cannot afford to monitor trends in the numbers of rodents with hantavirus infection, or assist border communities in Mexico with monitoring efforts that may provide a window on the emergence of diseases such as dengue fever or cholera.

In the area of laboratory services, there is a particular need for adherence to standard laboratory analysis practices, in part because of the unique role of the public health laboratory. For example, the molecular characterization of pathogens is not a clinically relevant test and is typically not supported in the private sector. Moreover, these tests can be costly because of the equipment, specialized reagents, and skilled technical staff that are required. Yet these tests are a critical weapon in the public health armamentarium as a means of combating emerging infectious disease outbreaks because modern epidemiological investigations rely on the modern laboratory tools of molecular biology for outbreak investigations. Coordination and collaboration between public and private laboratory services and the use of specialized diagnostic tests need to be encouraged and adequately supported financially and politically. This collaboration extends to regulatory

agency laboratories which feed into PulseNet and similar team efforts, and work to identify sources of foodborne outbreaks.

Coordination and communication will become increasingly important as new partnerships are created and old partnerships are renewed. This will especially be the case if a national commitment to maintaining a disease surveillance network and ensuring its readiness through standardization, proficiency testing, and support of a staff of trained health care professionals is upheld. It is in the areas of coordination and communications where a future role for public-private partnerships that have not existed previously may be found. Partnership of public and private entities will likely create new opportunities in infection control and fiscal support for public health activities. A strong commitment to the development of a national surveillance network and the strengthening of partnerships between the public and private sectors needs to be made.

Communication, Coordination, and Education and Outreach

Clear communication is an essential function for effective coordination across the public health sector to prevent and respond to disease outbreaks. It is also a key element in the fight for sustained financial support of public health activities. The components of public health and the core capabilities required to maintain public health at multiple levels need to be understood by policy makers, regulators, and public health professionals. A uniform process for communication of the elements of public health can provide guidance as to the best means to leverage opportunities among the public, academic, and private sectors, especially by professional organizations. Although such communication and uniform processes exist between federal and state public health systems, timely coordination and implementation within states needs strengthening.

Barriers to effective and timely coordination and communication have their roots not only in inadequate information technology but also in underqualified and transient personnel. Continuing education and training programs developed from an advocacy group perspective and targeted to the promotion of public health surveillance within states may generate the intellectual and financial commitments needed to strengthen the public health infrastructure. In this case, opportunities exist for the private sector to participate in the direct support of the infection control infrastructure.

For public health surveillance to be effective, there must be a free flow of information among federal, state, and local agencies, as well as between the public and the private sectors. Competition among and within the sectors is not necessarily desirable and, in fact, can be detrimental to public health surveillance activities. Agencies charged with conducting disease surveillance and responding to the surveillance findings need to have well-established communications systems that can facilitate the timely collection of surveillance data and

transmission of alerts about emerging infections across the country. The systems must also be able to share rapidly the information with those who need to know. These communications systems are hampered by the need to transmit information across state lines, to federal agencies, and to a variety of local and intrastate groups, including health departments, other state agencies, laboratories, emergency departments, hospitals, physicians, the public, and the media. Too often, however, communications systems at the state and local levels are outdated, situational, and low budget. Few assessments of their sufficiencies have been conducted, and no standards or guidance for the development of such systems exist. In addition, many state governments are further hampered because they have little information on technology capability and are discouraged from developing it because of downsizing.

Opportunities are available, however, to improve communications channels between the scientific and policy-making communities, among all levels of government, among professional health care organizations, and between public health officials and the public. This requires intellectual, political, and financial commitments. It requires resources dedicated to the training of individuals who deliver public health services. Effective sharing of information obtained from population-based surveillance and control efforts also needs the same commitment. The education of clinicians who must report the data and care for patients must not be neglected. Likewise, the development of more streamlined, accurate, and standardized medical record keeping is needed within and between the public and private sectors.

Strategic Planning, Resource Allocation, and Economic Support

Many improvements in the health of Americans have been achieved through public health efforts. Vaccination programs, safe food and drinking water, and responses to disease outbreaks are among the advances in public health that prevent untold morbidity and mortality and improve the quality of life. The American people value public health, and many see the core functions of public health as essential services that are provided by federal, state, and local governments. However, when the public health system is functioning well, it is invisible to the public and is taken for granted.

The U.S. Congress is generally supportive of public health activities that involve emerging infectious diseases. The general message received by Congress is that research is good for everybody and that research will make people healthier and will save Medicare dollars. There is, however, competition for research funds. Policy makers and the public identify with diseases. The most successful groups receiving research funding are those that are disease-specific, such as groups advocating funding for cancer or diabetes research.

The various components of the public health system are difficult to explain and promote to the public and to those who appropriate funds. Furthermore, infectious diseases are not seen as a health threat to Americans but, instead, are seen as a problem primarily faced by people in other counties. It is thus difficult to communicate the urgency and importance of maintaining current infectious disease prevention and health promotion programs to meet future infectious disease threats, especially when the public does not perceive infectious diseases to be important.

Consequently, public health is poorly understood by the public and by policy makers and decision makers. Despite a renewed attention and appreciation of the critical role of public health and the expanding demands of public health, public health programs have been dramatically underfunded, with less than 1 percent of the $1 trillion investment from health care going to support public health functions. For fiscal year 1999, the Senate Appropriations Committee is able to devote a $3.2 billion increase for the agencies of the Public Health Service, translating into a 14.5 percent increase from previous fiscal year (Jack Chow, Labor, Health, and Human Services Subcommittee, Senate Appropriations Committee, personal communication, November 1998). Public health's fiscal survival depends on categorical funding streams that may vary at the state and local levels and on unique investments that states and localities choose to make in supporting surveillance activities. Its fiscal survival is also affected by the chance that leadership may change in the state or local health department.

Because the public health system is highly fragmented, a renewed commitment to a national approach to public health and infectious disease surveillance with well-defined roles for state and local governments is in order. This is needed to support both new requests for funding and the full range of infectious disease issues that confront public health today. If the public health system is to care for the public's health, the focus cannot be solely on health care delivery systems. It is important that the public and policy makers are aware of the range of often unique services that public health can provide to promote health and prevent diseases.

Advocating for public health is often difficult, especially if those people and organizations that are best suited to be advocates are understaffed, have inadequate resources, may have real or perceived limitations on their ability to lobby, and are not experienced in the art of advocacy and communication. Yet, members of the U.S. Congress, state legislators, and managed care organizations must be educated about the needs of the public health system, particularly the public health infrastructure and its role in combating emerging infections.

Emerging infectious diseases are but one concern of the public health system. In addition, the issues that surround emerging infections are different from those of other public health concerns. Until public health laboratories and clinical departments have the resources and infrastructures necessary to meet the

challenges of emerging infectious diseases, planning will remain reactive rather than strategic.

A common language targeted toward policy makers and patients would be a first step to communicating effectively the challenges that the public health community faces in its struggle to build and sustain the necessary infrastructure to combat emerging infections. Short, succinct, nontechnical dialogue with the public and decision makers is needed when advocating for greater core support at the local, state, and national levels.

STRENGTHENING THE CAPABILITY

The workshop presentations and subsequent discussions converged on the overriding need to strengthen and support the core capability of the public health systems for infectious disease surveillance, response, prevention, and control. Variations in the capabilities of public health departments to detect and respond to disease outbreaks point to the need for public health departments at all levels to define their core capacities for epidemiological investigations, particularly as those capabilities relate to the activities of the public health laboratory. For example, surge capacity in response to an outbreak is one area in which the public health laboratory can begin to define its core capability and standards. Improved communication and collaboration between the private and public sectors may enhance the core capability and bridge the gap between clinicians and public health practitioners. The need for collaboration among disciplines and the need to bring in new partners from commercial laboratories in particular and nongovernmental organizations in general, emphasize the fact that additional resources will be needed to implement new mechanisms to provide for the public's health.

Opportunities are available, however, to improve communications channels between the scientific and policy-making communities, between the local and state levels and the national level, among professional organizations, and among public health officials and the public. This requires intellectual, political, and financial commitments. It requires resources dedicated to the scientific training of individuals involved in the delivery of public health services, to effective sharing of information from population-based surveillance and control efforts, to the education of clinicians who must report the data and care for patients, and to the development of more streamlined, accurate, and standardized medical record keeping.

The discussions at the workshop emphasized three cross-sectoral thematic areas in which carefully placed investments could make a positive contribution toward improving the core capability of public health systems to respond to emerging infections. These areas are assessed below.

Creation of a National Infectious Disease Surveillance System and the Integration of Public Health Systems

Nationwide, there are 50 to 60 different infectious disease surveillance systems. Competition among disease surveillance systems is not necessarily desirable and, in fact, can be detrimental when it concerns disease surveillance. The need to integrate national, state, and local public health systems, including those from the private sector, is one of the most daunting challenges confronting epidemiological investigations and laboratory surveillance. An unexpected disease outbreak or act of bioterrorism, the role that microbes play in chronic diseases, and the blurring of the traditional distinction between infectious diseases in hospital and community settings stress an already fragmented public health system.

The public health capacity and supporting communications systems necessary to respond to these challenges vary wildly among states, particularly among county and local health departments, and across the private sector. Variations in public health capacity may especially be the case between a state's large major metropolitan health department(s) and rural health departments. Among the key problems are inadequate integration and the capacities of existing communications systems to report emerging infectious diseases. Moreover, there are no guidelines for communications systems or for communications technologies for public health surveillance within and between the public and private sectors.

Given the variation found within and across the public and private disease surveillance systems, the identification and reporting of infectious diseases remain responsibilities shared between national laboratory networks and state facilities. In this regard, Internet-based communications systems can serve as invaluable tools that have the promise of linking local and state health departments, managed care organizations, and federal agencies responsible for infectious disease surveillance and response. The rapid exchange of information through the Internet could be the mechanism needed to strengthen the infrastructure for a nationwide infectious disease surveillance system and facilitate a means of disease data collection in real time.

A rapid, electronic, nationwide communications surveillance network linking public- and private-sector disease surveillance activities would promote information sharing, help develop algorithms for disease identification and response, standardize protocols for biosafety, support a national laboratory training network, and improve the capability to detect multistate outbreaks in real time. A national surveillance network for infectious diseases should take into account the diverse uses of data, methodologies, and approaches; the anticipated needs and scope of laboratory testing; new technologies and research results; and the ways in which priorities are set at different levels of government and across the private sector. A national surveillance network developed with these considerations in mind would provide an invaluable resource in retrospective and prospective analyses for disease surveillance purposes.

Although there are common uses of surveillance data at the local, state, and national levels, the emphasis on these data varies. For example, investigation of individual cases is critical at the local and state levels but less so at the federal level (unless a disease outbreak occurs across state boundaries). On the other hand, evaluation of larger-scale prevention and control measures (for example, the impacts of new vaccines) is a high priority at the federal level. A national surveillance system should take into account this diversity in the uses of data, approaches, and emphases at the different levels of government. Along with these benefits of Internet-based information systems, however, patient confidentiality must be carefully considered.

Modern infectious disease surveillance needs to move beyond traditional paradigms of disease surveillance and reporting. A nationwide infectious disease surveillance network will involve a unified strategy for epidemiological investigations in which the infection control community, the media, and informed public work more effectively at the state and local levels. It will need to better incorporate research results and new technologies as they become available from a wide array of sources. It will require an integrated public health system that collectively helps evaluate the public health implications of a disease uncovered during an outbreak investigation while data are still being gathered. These new data can provide impartial advice for timely and appropriate prevention and regulatory actions.

Specific considerations promoting the integration of public health systems toward the development of a nationwide infectious diseases surveillance system are discussed, as follows:

- **Increase the use of novel surveillance systems and modeling techniques to help predict, detect, or monitor disease trends, environmental and climatic conditions, or genetic shifts that suggest disease outbreaks and facilitate epidemiological investigations.** Improved methods are needed to identify the risk factors associated with disease outbreaks. Better understanding of the root causes and determinants of outbreaks can then be used to initiate prevention programs and mitigate the impact and spread of an infectious agent. However, to protect the public from emerging infections, it is not sufficient to culture only contaminated specimens, determine the nucleotide sequence of a pathogen or its isolate, and identify a new pathogen from an infected individual; rather, surveillance activities should examine the continuum of disease. Surveillance is becoming increasingly complex owing to a number of factors, including the change and loss of habitats worldwide, the interaction of humans with animals and disease vectors, and increased global travel. Although some intermediaries of disease are monitored (e.g., chickens and encephalitis), most are not. Although the monitoring of vectors (e.g., the tiger mosquito) is inadequate, it can serve as an early-warning system for human disease. Ideally, surveillance should have the capacity and scientific capability to monitor human

health in light of pathogen mutagenicity and changing environmental factors. Likewise, the utilities of biological, ecological, environmental, climatic, and behavioral factors need to be validated for the development of new algorithms and other analytical methods that can be used to forecast disease outbreaks.

- **Protect the confidentiality of medical records and preserve the mission of public health.** The need to enhance the disease surveillance capacity of public health systems and the need to communicate this information is confounded by the need to protect patient privacy. Public unhappiness with managed care and concerns about the confidentiality of medical records have recently focused attention on the need to develop better means to protect patient medical records and medical information. However, quality disease surveillance often requires the use of a name-based data system to track individual cases of disease. A means of ensuring the ability to conduct quality surveillance and, at the same time, the appropriate protection of patient and consumer information is needed. The impact of systems and legislation designed to protect patient confidentiality in association with infectious disease surveillance remains to be determined.

- **Define the minimum communications capacities and technologies needed to respond to infectious disease epidemics and pandemics, whether they occur naturally or are purposefully induced.** The establishment of a system that assesses and responds to the health needs of a population cannot simply focus on health care delivery systems. Responses to new disease threats, ranging from naturally occurring outbreaks to bioterrorist activities, will require unique services that the public health system can provide to promote health and prevent disease. Defining these mechanisms to build a fundamental, integrated capacity for infectious disease surveillance and communication will lay the foundation for a first line of detection and response to potential bioterrorism incidents or the threat of influenza pandemics.

- **Develop intrastate and interstate integrated communications systems as part of a nationwide infectious disease surveillance system.** Frequently, communications systems at the state and local levels are outdated because of funding, technological, or situational constraints. For example, funding limitations in some health departments currently rely on surface postal delivery and direct oral communications as the standard means of communication at the intrastate level for all messages except those that are most urgent. Conversely, interstate and national communications rely on video- and teleconferencing to relay high-quality information. Moreover, few standards or little guidance have been established for the creation of uniform criteria for effective disease reporting, and communication systems.

On the technical side of communications, public health systems need to be fully integrated with modern computer information systems. Internet-based communications systems have the promise of linking local and state health departments, hospitals, managed care organizations, and federal agencies respon-

sible for infectious disease surveillance and response. The rapid exchange of information through the Internet could be the mechanism needed to strengthen the infrastructure in infectious disease surveillance and data collection in real time. Along with the benefits of Internet-based information systems, however, the issues surrounding patient confidentiality must also be carefully considered.

The opportunities of computerization in the context of a failing public health system should not allow one to be seduced into a sense of accomplishment, however. The Internet is still limited as a communications tool within states and many health care professionals and institutions do not have access to it. Except for academic health centers, most health care providers, emergency departments, and hospitals do not have Internet access, much less a centralized e-mail system.

Further consideration must be given to the validity of the information shared. Rapid linkage of public health departments and laboratories with other health care providers, managed care organizations, and national centers is only as valuable as the quality of the data collected and the capacities of the epidemiological and laboratory surveillance systems. The establishment of standardized and integrated disease surveillance databases is one of the first steps that will require intellectual, political, and financial commitments to develop the art of a nationwide surveillance system. Already there are a variety of disease surveillance databases found nationally, within health departments, among hospitals, and across the managed care systems. Rapid communication combined with common algorithms for pathogen and disease identification, adherence to safety protocols, and recognition of an outbreak highlight the growing complexity of and difficulties with the integration of public health databases for disease surveillance purposes. Given the current trends of downsizing within state and local health departments, it is unlikely that intrastate communications will improve unless there is increased political will and financial commitment.

- **Determine CDC's capacity to review additional data, assess new situations, and determine appropriate responses if CDC investigators have already been diverted to other disease outbreaks at domestic or international sites.** Previously unrecognized diseases are appearing with alarming frequency, both domestically and internationally. Placed against a background prevalence of known diseases, outbreaks of unknown origin place a severe strain on any public health agency. This is particularly the case given that there is a nationwide dearth of well-trained and experienced health care professionals capable of investigating exotic pathogens. Because of the impacts of disease outbreaks on health, economies, trade, transportation, and national security, the capacity of CDC to respond to multiple disease outbreaks needs to be evaluated. Similarly, an assessment is needed on how to achieve better coordination among CDC, state health departments, and regulatory agency (FDA and FSIS) field investigative teams.

- **Develop communication systems to facilitate the ability of large commercial laboratories to rapidly share data with multiple jurisdictions.** Each public health laboratory resides in a fairly unique health care and public health system, and each operates a fairly unique information system. Problems of further fragmentation of a system of laboratory networks are evident as laboratories—whether they are local, commercial, or public—conduct increasingly smaller numbers of routine tests for the diagnosis of infectious diseases. The need to communicate or share data with collaborating or other laboratories therefore becomes less frequent. Thus, the traditional system of communications and maintenance of the collegial relationships that fostered the exchange of information and disease reporting are similarly breaking down. Electronic linkages with large commercial laboratories and health care providers in the community, with the national centers and reference laboratories, and within a health department and across jurisdictions will be key to effective infectious disease surveillance.

Investment in Human Capital

Without a clear commitment to invest in human capital, the entire fabric of the public health system is ineffective. One cannot object to the need for sustainable systems, interconnectivity, communication, capacity, advocacy, and planning; however, a dearth of public health professionals trained in epidemiology and surveillance is presently a concern. Some of the factors that contribute to this shortage include inadequate salaries, staff development, resources, and academic partners and a lack of an appropriate curriculum, as well as a lack of a multiyear grant or budget cycle that has the potential to create an incentive for state and local health departments to invest in personnel. It is therefore vital that programs that teach population-based science to trained health professionals in epidemiology and surveillance be developed along with programs that retain these professionals in state and local health departments. The following items were identified as providing a possible framework for accomplish these objectives.

- **Develop targeted public health training programs.** Building the public health workforce requires two interrelated actions: (1) development of the future workforce, and (2) retention of the workforce once it is trained for a career in public health. Historical distinctions between public health and medicine have resulted in the marginalization of public health by medical students and new physicians. Adequate exposure of medical students to public health activities so that they may consider the possibility of a career in public health, greater familiarity with the tools of public health, and promotion of an awareness of the role of the practitioner in the public health system all need further development.

Academic institutions and professional organizations are uniquely positioned to engage more directly with public- and private-sector organizations in designing

tailored training programs for their workforces. Training programs targeted to the public health and commercial laboratory workforce need to be strengthened. Academic health centers are also the intellectual hub for training public health professionals. Here there is an opportunity for increased investment in education and outreach for all health professionals in the area of emerging infections and, in particular, the area of antimicrobial resistance—conditions that are population-based. Multidisciplinary approaches are needed to educate medical and public health professionals on the pathobiology of infectious diseases.

Additionally, there is a lack of public health professionals trained in epidemiology, which undermines the capabilities of public health. Surveillance systems must be in place to ensure that state-level responses to outbreaks are adequate, appropriate, timely, and efficient. To respond to and investigate these outbreaks, adequate resources are necessary at the local, state, national, and international levels. Resources include not only computers, laboratory equipment, and environmental monitors but also adequate numbers of trained epidemiologists. Investments must be made in the training of new public health professionals and in the retention of experienced professionals.

The need to better communicate public health matters to the public and policy makers is clear. However, one of the problems facing the public health system is a sense of continuity and leadership reflected by a continuation of individuals in public health roles. Reports from the Association of State and Territorial Health Officials reveal that the average time of service for a commissioner of health is less than 2 years. Many of these positions are filled by political appointees who have some experience in health—often in health care delivery or disease care delivery, but not in public health. The leadership provided by a public health commissioner affects the role of public health departments in the changing picture of the health care system.

- **Promote linkages among academia, the medical community and the public health sector.** Efforts that support linkages between academic public health institutions and professional organizations could help encourage the practice of public health as a chosen academic profession. Currently, population-based sciences such as epidemiology and concepts of surveillance are not mainstays in health professional training. However, academia is equipped to provide continuing education in these areas. Collaborative research between academia and public health departments needs to be more strongly encouraged and funded. Because practicing physicians require greater awareness of issues related to emerging infections, disease reporting, and population-based health, it is essential that creative and innovative continuing education programs be developed by public health, organized medicine, and academic communities. Academic institutions must engage more directly with public- and private-sector organizations in designing training programs tailored for their workforces.

Changes in the health care system are causing concerns about the traditional way in which disease surveillance is conducted. Traditional patterns of reporting

are lost as the source of health care delivery shifts from the inpatient to the outpatient setting. Lost is the dedicated epidemiological reporting system found within the inpatient setting. Cost-containment factors, increased patient loads, and new demands in the outpatient setting are placing increased pressures on providers' time and expertise. The resulting trend of the greater use of empiric treatment, which helps to alleviate some of those pressures, may actually be decreasing the level of reporting of information on infectious diseases. A critical issue then becomes the role of the physician in public health and infectious disease surveillance. Efforts to increase the linkages between the medical and public health communities are needed early in the physician's training and throughout his or her career.

Cultural and conceptual gaps exist across the various disciplines that need to be more allied in effective public health practice and research. Key elements for an integrated public health system include basic laboratory research, epidemiological research, clinical research, behavioral research, health care services and health care policy research, and education and public outreach. The historical disconnect between academic public health and the larger health care sector must be repaired so that the responses to emerging diseases are more effective, particularly as this disconnect pertains to private health care delivery systems and diagnostic laboratories.

- **Funding sustainable careers.** Efforts need to be made to reconsider yearly line items in budgets for investments in personnel. One-year grant cycles do not encourage investments in recurring costs, such as personnel. A more creative approach to grants and grant cycles needs to be considered to give states and local health departments an incentive to invest in human capital. In addition, steps must be taken to encourage revamping the 1-year grant cycles to invest in personnel. One-year grant cycles do not reinforce investments in recurring costs, such as personnel.

Sustainable careers are also dependent upon the development of regional capabilities for training, interpretation, problem solving, and improvement of information technologies, as well as regional approaches to planning, as a practical solution to limited resources and disparate state and local laboratory capabilities. It is difficult to develop the kinds of career ladders within public health that are important to the retention of good people. Support of regional capabilities for ongoing training in continuing medical education is needed to promote careers in public health and create meaningful career ladders and opportunities for professional development. Additionally, regional approaches to planning should be encouraged as a practical solution to limited resources and disparate state and local laboratory capabilities.

There is also a need to expand CDC's Epidemiologic Intelligence Service (EIS) program at the state and local levels to train public health professionals in epidemiology and surveillance. In the area of foodborne-illness investigations

outbreak-related field activities included should be for the EIS officer with FDA and FSIS as part of the EIS training experience.

Finally, even though the PulseNet program has experienced many successes, it is stretched in its ability to subtype every isolate and to follow up with appropriate epidemiological investigations because of a lack of trained personnel resulting from inadequate funding. As such, more support is needed for this program in order for it to successfully reach it's ability to conduct timely sharing of information that can facilitate the recognition of an outbreak.

Improved Collaborations Between the Public and Private Sectors

A disconnect exists between the needs and abilities of the public and private sectors when it comes to disease surveillance. Although commercial interests have unique capabilities to conduct the type of testing required by the public sector, they do not have the incentives or resources. On the other hand, detailed epidemiological follow-up studies are most suitable for the public health sector. Both sectors have necessary roles.

Public-sector laboratories play an important role because of the unwillingness of private laboratories to voluntarily perform activities that will not make profits and because of the more direct accountability of public-sector laboratories to elected officials and the public. Despite these factors, public sector national laboratories need ample opportunities to collaborate with academic and private-sector facilities to help standardize databases and evaluate reagents and techniques. Such collaborations will be particularly important in response to changes in the ways in which health care is administered and as the need for cost containment continues to grow. For example, one area of collaboration is referred to as "split sampling" whereby partnerships are formed between public and private laboratories. Split sampling can be defined as follows. As the complexity of disease investigation increases, the complexity of laboratory testing increases and some necessary tests will remain relatively rare, expensive, and very scientifically precise. Therefore, to verify results, many specimens analyzed in a public laboratory may need to be split, with half of the sample sent to commercial laboratories for rapid analysis or for analysis with arcane, costly, and unusual rare reagents. Although split sampling is expensive and is an accepted standard for samples whose results will require legal or regulatory action, it is not reimbursed by traditional health plans. Nevertheless, isolates and specimens examined by split sampling, an essential procedure to confirm the presence of a specific pathogen, come from various health care settings. Specific opportunities to promote public-private sector collaborations include:

- **Leverage the potential advantages of working with managed care.** The transformation of the health care system has created an adversarial relationship

among public health officials, managed care organizations, and state legislators. For example, an overemphasis on economic efficiency and cost containment creates disincentives for disease reporting and isolate submission. In addition, contracts with large national commercial laboratories may create barriers to complying with state and local disease reporting requirements. Yet, a common issue underlying these negative effects of managed care is the lack of adequate funding for support of the public health infrastructure. Managed care plans have integrated databases that could be used by public health systems to track infectious diseases among the plans' populations. Likewise, there is a potential for seamless communication between public and commercial laboratories, managed care organizations, and public health officials. The development of partnerships with managed care organizations may be one way in which public health laboratories could share databases and contain infrastructure costs. Additionally, standardized contract language could be developed to bind public health laboratories and managed care to foster partnerships.

- **Define the unique and complementary roles of the public- and private-sector laboratories and identify their core capabilities.** States and large local jurisdictions must have the expertise and experience needed to rapidly mount laboratory investigations in response to disease outbreaks. Additionally, federal agencies with outbreak-related laboratory missions, including CDC, FDA, FSIS, and DoD, need to have an adequate level of expertise to rapidly identify new threats which emerge. Public health laboratory expertise is one function that should not be fully privatized because the role of government in protecting the nation's health will inevitably determine laboratory investments. However, the competitive environment of managed care, the growth of independent laboratories, and the consolidation of hospital laboratories influence some of the important shifts in the capacities of public health laboratories. A means of fostering closer partnerships between public and private laboratories is needed to help develop compatible surveillance and reporting systems. For example, public health departments could receive data on disease incidence from the private sector. These data would then be integrated into a larger national public health surveillance system. Special emphasis could also be placed on hospital emergency departments, which are frequently vital sources in the reporting of disease outbreaks. Coordination of these capabilities will become a key element to determine where the locus of activity should lie for a given disease or outbreak situation.
- **Regionalization of state public health laboratories.** The functions of the public health system are highly fragmented across national, state, and local levels, as well as between the public and private sectors. Use of strategies such as cost subsidization for certain routine tests and for more specialized kinds of services is one way in which public health laboratories are trying to remain economically viable and yet sustain their responsibility for infectious disease surveillance. Some public health laboratories are also focusing some of their efforts

on various activities that have importance for government functions. This has created dilemmas for state and local public health laboratories in terms of where they should set their priorities. It may be time to consider the regionalization of state public health laboratories. Areas of focus for such regionalized public health laboratories would be the use of certain kinds of expertise and specialized capacities that have limited commercial value but that have enormous consequences for public health and safety. A renewed commitment by the public and private sectors to a coordinated national approach to public health and infectious disease surveillance is needed to support new requests for funding and to sustain the full range of infectious disease-related activities that confront public health today.

- **Systems to evaluate diagnostic reagents and techniques.** Comprehensive infectious disease surveillance is beyond the capacity of any one laboratory, whether it is public or commercial. For example, adequate evaluation of diagnostic reagents and methodologies and ensuring that the techniques used are the most appropriate for the assumptions of the test are labor- and resource-intensive. Yet, laboratory results, results of data analyses, and interpretations vary if standardized techniques are not followed. Specialized techniques in modern biology and the skilled personnel needed to perform those tests are usually too costly for most laboratories but could be obtained through the use of a regional system and private-public partnership. A unified system of sharing materials and methods would be an invaluable tool for rapid communication, pathogen and disease identification, establishment of protocols for safety, and enhancement of the ability to detect multijurisdictional outbreaks.

- **Educate members of the U.S. Congress, state legislators, and governors about public health activities and indicate to these individuals that mere additions to, or extensions of, existing categorical funding are insufficient to meet the public health system's needs.** The U.S. Congress has come to appreciate the value of basic research and could similarly come to appreciate the need for an adequate public health infrastructure and nationwide system for infectious disease surveillance. Issues related to emerging infectious diseases, including bioterrorism, food safety, antimicrobial resistance, and vaccination programs, could be used to promote the need to build the fundamental capacity for integrated infectious disease surveillance as an important first line of action in detecting and responding to infectious diseases. This is an opportunity for the public health community to create partnerships with patient advocacy groups.

- **Expand private sector investments in public health research so that public health services, applications, and prevention research are funded at sufficient levels to accommodate discoveries derived from basic research.** The driving force behind advances in disease surveillance, prevention, and response is a vigorous and multidisciplinary basic and targeted research enterprise. Public, policy makers, and public health practitioners need to stay informed about recent research results and applications of discoveries related to understanding of diseases. The timely analysis and dissemination of surveillance data

gathered through public-private sector collaborations could promote better patient care. Physicians could be better informed with the latest medical information and better able to provide their patients with the most appropriate care and, at the same time, reduce the risk that an infectious disease is spread to the larger community.

CONCLUDING REMARKS

The changing face of health care poses new challenges for the detection, treatment, and prevention of infectious diseases. Historically, public health departments, hospitals, and clinics have been the main sources for the detection and treatment of infectious disease outbreak. State and federal laboratories have been the driving force behind surveillance. The function of the public health system is diffuse, with managed care organizations and industry playing new roles. All of this comes at a time when the communications potential is enhanced by the existence of the Internet and large, accessible databases. These combined forces simultaneously place new pressures on and offer new opportunities to the public health system. Yet, the basic infrastructure of the public health system, particularly at the state and local levels, is eroding. With that deterioration comes a diminished capacity to predict, detect, and respond to an emerging infectious disease.

An adequate public health system is made up of various components. Although the list presented below is not comprehensive, it nevertheless provides a good representation of the components that should be considered. The changing demographics and environmental conditions that the United States and countries around the world are experiencing have important influences on public health and include global travel; immigration and migration; movement of products, including food and other potential vectors of disease; population growth; urbanization and crowding; changing socioeconomic conditions, particularly the worsening poverty observed in so many areas of this country and other parts of the world; and significant ecological changes such as deforestation, reforestation, irrigation, and changing patterns of agricultural and pesticide use. These changes are dynamic and contribute to the complexities of emerging infectious disease outbreaks.

Because of such events, the need for the development and implementation of a fundamental capability for infectious disease surveillance at the community, state, and national levels cannot be overemphasized. Uniformity needs to be established in the currently fragmented public health systems, particularly in the public health laboratories that exist throughout the country. If the United States is to have a robust public health system, ongoing training and the creation of meaningful career ladders and opportunities for professional development within the practice of public health need to be established and considered priorities.

Additionally, public health systems must be completely integrated into the computer age. The current standard for laboratory reporting in most state health

departments is still surface mail, with a measured 10- to 14-day lag time in some states. To speed up the reporting process, public health systems need to seriously consider application of computer and electronic communications technologies to their laboratory reporting systems. It is also critical for health departments to have electronic linkages with other health care providers in their communities and with national centers such as CDC, as well as to explore the issue of data integration and data comparability both across systems within a health department and across the various levels of the public health systems.

Public health systems also need to enhance their capability to communicate critical information, particularly information about the risk of an infectious disease outbreak. Intrastate communications systems are often underdeveloped, lack standardization, and are rate-limiting steps in some forms of communications. The development of laboratory listservers would increase real-time connections and therefore enhance the communications capabilities to detect, assess, and respond to emerging infections and outbreaks. Public health systems also need to further explore and have the capacity to have Internet-based bulletin boards for the reporting of information on emerging infections. The electronic and computer media are also especially important for clinical laboratories since this would enable clinical data to be manipulated into a form in which it could be sufficiently standardized and shared among institutions and organizations. This process could begin to facilitate everything from public health surveillance activities to clinical trials that require cross-institutional coordination and cooperation. These actions would promote the development of a much-needed national disease surveillance system.

Public health systems must also embrace the human component. They need to attract and maintain a cadre of public health professionals who are well educated and knowledgeable about technologies. Training opportunities must be made available to these professionals to keep them up-to-date on pertinent issues that would increase their knowledge and capabilities on public health issues, including surveillance and epidemiological investigation issues. Additionally, to attract and retain these professionals, public health systems must be willing to compensate them adequately. Salaries need to be competitive not only for public health professionals (including epidemiologists and laboratorians) but also for the information technology personnel who work in the public health arena. For example, many hospitals cannot compete in the current technology marketplace for the best networking and computer experts because high-technology companies can provide them with much more competitive salaries.

Lastly, the public health infrastructure should contain a number of qualitative features. Not only does it need to be sustainable but it should be adaptable and capable of anticipating future problems. An adequate public health system should also have an infrastructure that can quickly adjust to a given portfolio of problems and that should be resilient, transformative, and able to be revised when necessary.

1

Introduction

BACKGROUND

In the mid-1970s, many in the medical community were confident that the war against infections diseases was nearly over. Infectious diseases were on the wane, powerful antibiotics were proven weapons in the armamentarium against bacterial infections, smallpox was on the verge of eradication, and new vaccines were being developed to combat a variety of diseases. These improvements to health were accomplished through advances in public health. The public was well aware of these advances and the amazing results produced by medical science but did not necessarily view them as a function of public health. Nevertheless, the public's knowledge led patients to have greater expectations of their physicians and reinforced the concept of entitlement, that access to health care services of good quality is a social right of every citizen.

Governments felt the pressure to make modern medicine more widely available and responded to the appeals of their citizens. Concerns over substance abuse, chronic diseases, tobacco use, teenage pregnancy, environmental pollutants, and geriatric disorders captured the attention of decision makers. Public health systems were expected to address these complex, challenging, and diverse problems facing the public, as well as to continue to perform their traditional roles in disease surveillance, responding to epidemics and preventing infectious diseases. Yet, the integration of these new roles was poorly defined, inadequately supported, and not fully understood.

Today, the public health system is at a crossroads as to how to define and sustain its role. The changing face of health care poses new challenges for the detection, treatment, and prevention of infectious diseases. Historically, local public health departments, hospitals, and clinics have been the main source for

infectious disease outbreak detection and treatment. The members of managed care organizations and the rate of privatization of public health laboratories continue to increase in response to the needs of the communities they serve. Simultaneously, many of the specific functions of public health laboratories and institutions that provide epidemiological services may be being eroded. Along with that erosion, local public health systems may have a diminished capacity to detect and respond to emerging infectious diseases. Additionally, the public healthy system's capabilities may also be adversely affected by the growing number of the uninsured population that focused most of the burden for resources on the public safety net and public laboratories. The challenge for public health laboratories will be to implement cost-shifting or to obtain new sources of support.

As expected, conflicts arise in public health and its priority setting as it moves away from its traditional focus on infectious disease control to address the evolving fields of chronic diseases and injury prevention. Each of these areas is consistent with the overall mission of public health. Unfortunately, they are all vying for the same available resources.

For years, the public health system has been challenged to respond to a variety of new and reemerging disease threats, from Legionnaires' disease, to HIV infection, to Lyme disease, and, now, to the latest onslaught of reemerging infections such as those caused by organisms that are resistant to antibiotics. The enduring problems of chronic illness and injury, the rising specter of environmental pollutants, and the transformation of the nation's health care system provide strong incentives for public health to develop innovative systems for infectious disease surveillance and response.

Privatization of health care and public health laboratories poses significant challenges to the traditional way in which disease surveillance has been conducted. Essentially, this has resulted in high-volume, low-cost analyses migrating to the private sector, while low-volume and high-cost tests remain in the public sector. Changes in the health care system are posing significant concerns for the traditional way in which disease surveillance has been conducted. For example, Medicaid patients, whose health data were once easily available to public health officials, are now being increasingly served by the private insurance industry (most commonly, managed care), which may not have the same incentives to share data. A reevaluation and an alternative means to maintain those important elements that have been effective and that continue to be effective for infectious disease surveillance are needed. The challenge will lie in how we in the public health care system can best work with the changing health care system to create a stronger and more appropriate surveillance system. The opportunity will be to promote public health and its special role and importance in health care.

CHANGING LANDSCAPE OF PUBLIC HEALTH

Adapted from a presentation by Margaret Hamburg, M.D.
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The issue of emerging infectious disease in the changing landscape of public health requires a focused examination of the factors that have changed the nature and extent of human exposure and risk entailed by the agents that cause infectious diseases (IOM, 1992). The changing demographics and environmental conditions both contribute to the emergence or resurgence of infectious diseases. Likewise, global travel, migration, trade and commerce, and changing socioeconomic conditions affect transmission of infectious diseases. Human behaviors, such as dietary habits, food preparation practices, poor personal hygiene, unsafe sexual behavior, and intravenous drug use, also contribute to disease transmission. The overuse and misuse of certain pesticides has led to the resurgence of a range of important disease threats in the United States and, perhaps more significantly, worldwide.

Recently, certain health care practices have also contributed to the problem of emerging infections. Among these practices are the increased use and intensity of certain health care services, including invasive medical procedures and immunosuppressive therapies, and the overuse and misuse of antibiotics, leading to a broad range of concerns about the development of antimicrobial resistance. Concomitant with these changing practices is the transformation of the health care delivery system and the emergence and deepening penetration of managed care.

Delivery of Clinical Services

The delivery of most clinical services has shifted largely from the inpatient to the outpatient setting, and physicians are increasingly providing empiric treatment rather than relying on laboratory tests for confirmatory diagnosis before initiating treatment. Reliance on empiric treatment, however, decreases the completeness and accuracy of disease reporting and, when coupled with the availability of fewer routine laboratory tests, results in the loss of traditional means of disease reporting and approaches to disease management. These changes have compromised our ability to accurately monitor and respond to emerging disease threats.

Another area of change in the health care arena is the evolving role of many public health departments in the delivery of clinical services. Providing health care services to underserved and indigent populations is viewed by many as an important role of public health departments, as part of the health care "safety net". Alternatively, some public health departments have focused their efforts on providing a more limited set of clinical services that are important for

overall disease control objectives, for example, providing directly observed therapy for patients with tuberculosis or antibiotic treatment for sexually transmitted diseases.

Each of the paths described above is important to the changing identity of public health and the future stability of public health systems. In particular, many public health departments are dependent on clinical activities and the revenues from those activities. Revenues from clinical care services often cross-subsidize some of the other important public health functions, such as surveillance. Thus, discontinuing clinical services delivery in health departments can destabilize the financial infrastructure on which many public health systems depend for financial viability. Yet, continuing to provide clinical services in light of the changing and increasingly competitive health care environment and growth of managed care, can also be a destabilizing force for many public health departments.

To be effective, health departments must look outside the context of clinical care delivery to a range of often unique services and functions that they can provide to promote health and prevent disease. For example, communication about the importance of the public health infrastructure in addressing the potential threat of bioterrorism requires vigorous effort. Increased funding to build the fundamental capacity for infectious disease surveillance is an important first step in the detection of and response to a potential bioterrorist threat.

The public health system is often fragmented and dependent on categorical funding streams at the federal, state, and local levels. One-time investments in public health activities, such as infectious disease surveillance, do not provide the consistent and sustained leadership and support needed to strengthen the public health system.

Laboratory-Based Reporting

The problems of a fragmented system of public health are echoed when one examines the plight of public health laboratories. For example, the structural mechanism of financing differs in each state laboratory. Each state laboratory resides within a unique health care and public health system, and each operates its own unique information system.

Public health laboratories are struggling to find their position and role in the changing health care environment. Some of the important shifts in the landscape are related to competitive market forces that promote the growth of independent laboratories and the consolidation of hospital laboratories. Many managed care organizations are contracting with laboratories that offer the lowest prices. These laboratories often differ across states. Consequently, conflicts arise when guidelines for disease reporting vary across jurisdictions. Cost-saving programs have also decreased the volume of samples and the numbers of tests that are performed because of the greater use of empiric treatment of diseases. Health

care systems no longer send their specimens to the traditional laboratory that they may have previously used. With the breakup of local laboratory networks and with the performance of fewer routine laboratory tests by public health laboratories, there is a concomitant breakdown in some of the traditional systems of communications and collegial relationships that foster information exchange and disease reporting.

Improving Communication of Health Information

Communicating the value and importance of the public health system is a perennial challenge in part because when the public health system functions well, it is invisible to the public and to public policy makers. The public health community must recognize that both policy makers and the public understand and respond to disease-specific issues. Theoretical issues in public health are not well understood by the lay public, but presenting clear, concise information about specific disease threats can help to communicate concepts of risk which are better understood by policy makers and the public. Communication of public health issues requires a strategy that reframes a number of important issues in terms that people understand. This is an important transition for public health, and the public health community must be positioned to maximize the opportunity to promote public health and its special role and importance in health care.

2

Epidemiological Investigation

OVERVIEW

Emerging infections continue to disrupt the health care system and are becoming increasingly complicated to detect and treat successfully. In addition, the public health system is continually reminded of the challenges posed by the unexpected, whether it is the next influenza pandemic or a bioterrorist act. In 1988 the Institute of Medicine (IOM) recommended that "every public health agency regularly and systematically collect, assemble, analyze, and make available information on the health of the community, including statistics on health status, community health needs, and epidemiologic and other studies of health problems" (IOM, 1988, p. 141). Thus, one of the essential public health services is the diagnosis and investigation of health hazards in the community. Health departments at the federal, state, and local levels, often with the aid of the academic community, can perform these functions if they have the appropriate level of resources, adequately trained personnel, and established systems of reporting and communication.

Each sector offers unique capabilities, and each sector faces some common and uncommon challenges, but most infectious disease outbreak investigations follow the same general approach: (1) identification of the circumstances that indicate the need for an investigation (e.g., more than the expected number of cases of a particular disease); (2) investigation; (3) determination of the cause of the circumstances (i.e., the reason that the excess cases of disease occurred); and (4) response, which usually includes the control of the outbreak, and recommendations and coordination of response—both public and private—for the prevention of further disease. Within each investigation are several components which may include, but are not limited to epidemiological, laboratory, and en-

vironmental assessments. Each component may also require coordination at several levels, from the local to the state, private, and federal. In general, federal resources, through the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA), are available to assist in investigations, but they only do so if state and local public health agencies have in place the infrastructure to detect and report unusual disease occurrences. Concise and timely communication between each component is critical to a good investigation.

NATIONAL PERSPECTIVE ON OUTBREAK INVESTIGATIONS

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Although the crises attendant with periodic infectious disease outbreaks serve as a reminder of the importance of public health, media attention on the successful investigation and control of outbreaks also contributes to the common misconception that the infrastructure available to meet public health needs is sufficient. However, although media attention has been instrumental in keeping many infectious diseases in the forefront of public consciousness, such misconceptions about the sufficiency of the infrastructure contribute to greater expectations on the part of the public and those who control resources.

Investigations are more complex in nature because of a variety of new pathogens and risk factors (e.g., travel, food imports, technological innovation) increased public and media attention, their significant economic and political consequences, and because they are more likely to cross state and international jurisdictional boundaries. The ability to quickly recognize and respond to widely dispersed disease outbreaks is a particular public health management challenge.

The tools available to recognize and respond to disease outbreaks have improved in recent years. There are now computerized databases which allow outbreaks to be more rapidly recognized, and electronic mail and the Internet allow information to be more rapidly shared. As one example, CDC now develops and shares with public health officials a weekly line listing of *Escherichia coli* O157:H7 outbreaks that have been recognized. This allows seemingly disparate outbreaks to be potentially linked. The development and dissemination of molecular fingerprinting has virtually revolutionized our understanding of the epidemiology of infectious diseases, and has been especially useful in outbreak recognition and investigation. This technology allows laboratories to subtype pathogens, and for foodborne pathogens, to electronically submit pattern analysis to a centralized database maintained by CDC. Real-time analysis of submitted data allows recognition of outbreaks when they are still small, and has al-

lowed us to recognize outbreaks which previously were unlikely to have been identified. Early recognition and prompt investigation has likely led to prevention of large numbers of illnesses, especially those related to foodborne disease. However, identification of outbreaks when they are small can prove a challenge for investigators to identify the source and risk factors.

In the United States, outbreak investigation and control is the responsibility of state and local health departments. When outbreaks are small and focal in nature, as they usually were in the past, this arrangement is adequate. However, it produces challenges in an era of a globalized food supply and international travel when outbreaks cross jurisdictions. CDC's federal role is to support the investigations conducted by the states and localities through the provision of technical assistance and resources. The most intensive CDC support is through the epidemic assistance (Epi-aid) mechanism where a team (including an Epidemic Intelligence Service epidemiological trainee) goes into the field to assist the state; there are also international Epi-aids.

However, CDC provides lesser degrees of assistance to state and local jurisdictions in hundreds to thousands of other outbreak investigations annually. This assistance can take a number of forms. One is provision of advice from technical and disease experts, who may go into the field to provide assistance. Another is through specialized diagnostic and laboratory investigations to determine the cause of illness or to subtype or sequence pathogens. CDC can also provide assistance in study and questionnaire design, and set up computer programs to enter data. CDC, in collaboration with the World Health Organization has developed an integrated DOS-based (but Windows™-compatible) free software package, Epi-Info, to assist in outbreak-related activities. The package allows the user to design questionnaires, and receive assistance in epidemiological study design, data analysis, and report writing. This software is used extensively both in the United States and abroad.

Finally, CDC can also provide assistance in implementation of control measures, including direct provision of materials such as vaccines or biologics. For example, if there is an outbreak of hepatitis A or B and the local jurisdiction has difficulty finding adequate supplies of immunoglobulins, CDC can help locate supplies in other parts of the country.

An increasingly important role at the federal level is outbreak coordination and notification of other jurisdictions about an outbreak. It is no longer uncommon for domestic outbreaks to involve 20 or more states, any one of which may have too few cases of illness to conduct meaningful independent investigations. Recent examples of such outbreaks include cyclosporiasis associated with imported fresh raspberries, salmonellosis associated with contaminated cereal, and listeriosis due to contaminated hot dogs. In such instances, consistent case definitions for illness must be applied, standard questionnaires must be employed, selection of controls for case-control studies must be similar, specimen collection and disposition must be consistent, and data must be shared and pooled.

Sister federal agencies also play a vital role in outbreak investigations, particularly the Department of Agriculture's public health agency, the Food Safety and Inspection Service (FSIS) and the Department of Health and Human Service's Food and Drug Administration (FDA). Both FSIS and FDA play a role in foodborne outbreaks because of their regulatory oversight of all food products, the former agency responsible for meat, poultry and egg products, and the latter responsible for all other food products. In 1997, FSIS's Office of Public Health and Science created the Epidemiology and Risk Assessment Division which includes eight field epidemiologists who assist states, local jurisdictions, and CDC with trace-back efforts during outbreaks where FSIS-regulated products have been implicated. In recent years, FDA has tried to improve the coordination of its response to multi-state outbreaks with CDC and other federal agencies. Because food-borne outbreaks frequently involve low-level sporadic contamination of widely distributed foodstuffs, often in food from other countries, FDA must deal with multiple federal agencies and jurisdictions. The FDA Division of Federal-State Relations aims to conduct outreach and coordinate such efforts.

CDC has attempted to enhance the capacity of state and local partners to conduct surveillance for disease outbreaks in a number of ways using resources allocated for emerging infectious diseases. One is through improved in-house laboratory and epidemiological expertise. The second is through provision of resources to state health departments. One category of support is known as Epidemiology and Laboratory Capacity (ELC) cooperative agreements, which states have used to build epidemiological capacity, improve laboratory infrastructure, and electronically link local health departments. The second category is the Emerging Infections Program (EIP) sites, which conduct more active disease surveillance and epidemiological studies, including the FoodNet system to monitor the incidence of foodborne diseases. The third category is the development of the PulseNet system for molecular fingerprinting of enteric pathogens.

Working with the Council of State and Territorial Epidemiologists (CSTE), CDC has developed a number of strategies aimed at accomplishing multijurisdictional investigations while respecting state autonomy. These include development of a coordination checklist, which allows state and local agencies to determine when to inform others of an outbreak and when the outbreak may have more widespread implications. CDC has also established a partnership with state epidemiologists to review available data during an outbreak and make determinations about the required public health response, as well as serve a quality control function by reviewing the investigation once it is concluded. These deliberative groups, which are ad hoc, serve the important purpose of aiming to balance local needs with national public health obligations. To allow better notification of potentially involved jurisdictions, CDC is developing a computer program known as Epi-X, which will allow users to input data on outbreaks in their jurisdiction into a centralized database, simultaneously informing other

public health officials of the occurrence. This should enhance information sharing and notification, and allow the development of a database on disease outbreaks, their risk factors, and control measures.

While these efforts have significantly improved the United States, ability to recognize and respond to disease outbreaks, there is still substantial room for improvement. Not all states currently participate in the ELC or PulseNet system, and their capacity to conduct investigations is limited. The international capacity for outbreak recognition and response is also spotty, although WHO is working toward improvements in this area. In the outbreak setting, successful investigations require a coordinated, rapid response. To the degree that one of the involved jurisdictions cannot meaningfully play their role, this goal cannot be completely achieved.

STATE PERSPECTIVES ON OUTBREAK INVESTIGATIONS

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One of the essential public health services at the state level has been identified as the ability to diagnose and investigate health problems and health hazards in the community. State health departments are often on the front line of outbreak investigations, and the information concerning potential outbreaks can come from many sources, such as the medical care system, public agencies, or other public health entities. At times, the recognition of potential outbreaks can be coincidental and informal such as two physicians realizing that they had seen patients with similar but unusual syndromes, as occurred with eosinophilia myalgia syndrome. At other times, the identification of an outbreak occurs via established public health surveillance systems. After the identification of a potential outbreak, the investigation starts to reveal the cause or causes of the outbreak, and in the end, recommendations are made to stop the outbreak and to prevent future illness.

Disease surveillance systems are usually population-based and can be either active (e.g., calling hospitals to find cases of eosinophilia myalgia syndrome) or passive (laboratories mailing reports of infectious diseases to the health department). Although, active surveillance is expensive, it usually results in more accurate data, but passive surveillance, even when only as few as 10 percent of cases are reported, can be adequate for tracking disease trends. Sentinel surveillance systems rely on reports of a few cases of disease whose occurrence suggests that preventive or therapeutic care efforts need to be adjusted. For diseases like influenza, sentinel surveillance can be relatively inexpensive and yet have the ability to obtain timely and valuable information.

A variety of diseases are made legally "reportable" to state health departments, a requirement that contributes greatly to the ability to track the health of the population under surveillance. These reportable diseases include infectious, occupational, chronic, and environmental diseases, as well as conditions such as injuries, birth defects, and cancers. Most state public health systems also require the reporting of outbreaks, unusual syndromes, and uncommon diseases, and include a provision that allows "emergency" or research-related reporting in special circumstances (e.g., to investigate the possible association between Guillain-Barré syndrome and influenza vaccination in the early 1990s).

Although each investigation is unique, most state-level investigations require basic components to ensure a timely and appropriate conclusion:

1. Epidemiological component. The determination of a cause of an outbreak usually requires the use of accurate epidemiological methods to ensure the collection of unbiased data, the use of appropriate statistical methods in the analysis of the data (often with the use of computer software such as *Epi-Info* [computer software developed by CDC]), and the correct interpretation of the analysis results.
2. Laboratory component. The ability to collect specimens, whether clinical specimens from patients, environmental specimens from food or water, or targeted specimens (such as the filter of a whirlpool associated with cases of Legionnaires' Disease), is a critical component of the investigation. The ability to have these specimens appropriately analyzed is often critical, particularly if regulatory authority needs to be invoked, for example, to recall food products on the market.
3. Environmental component. The information provided by the environmental health engineer's investigation is instrumental for determining what environmental risks were present. For example, the engineer's information can determine if the chlorination unit at the municipal water supply was working correctly or if the oven used to bake the casserole at a local restaurant was hot enough to kill all pathogenic bacteria.
4. Effective communication. The final and often most critical component is effective communication. The results of the investigation must be communicated and the appropriate individuals must be educated about the actions needed to reduce the risk of further illnesses.

Frequently, an incident that begins at the state or local level requires national response as it becomes evident that the outbreak has crossed state borders. An example of this occurred in the summer of 1996 when members of the National Guard from Iowa became ill after returning from 2 weeks of training at Camp Chaffee, Arkansas. When medical officials at the National Guard became aware of the situation, they contacted the Iowa Department of Public Health to report a possible outbreak, to solicit help in appropriate laboratory testing of

blood specimens, and to seek epidemiological advice. The symptoms reported by the members of the Guard were consistent with those of tick-borne illnesses, such as ehrlichiosis or Rocky Mountain spotted fever, both of which are known to occur in Arkansas but which occur only rarely in Iowa. The situation was complicated by the fact that many members of the Guard had donated blood after being exposed to the ticks, but before becoming ill, thus potentially spreading the disease to the blood recipients.

After the Iowa Department of Public Health confirmed that the illness was a tick-borne disease, CDC was contacted for assistance, since it became apparent that the Guard members from other states were also attending training sessions and the blood recipients, who resided in many states, were at risk of developing disease. CDC played an essential role by coordinating and assisting the investigations in several states and took primary responsibility for recalling and determining the safety of the donated blood. This investigation involved several states and CDC as well as other national entities such as the National Guard, the Red Cross, and other organizations concerned with the safety of the blood supply. The epidemiological investigation included interviewing ill and well members of the guard, obtaining blood specimens, and tracing donated blood units. The environmental investigation involved inspection of the Fort Chaffee site for the presence of ticks and other risk factors and the retrieval of ticks for identification and testing. The laboratory component involved testing of blood specimens from members of the guard, blood recipients, and ticks.

The results of the combined investigations were recommendations to the National Guard and Fort Chaffee on methods for reducing the risk of transmission of tick-borne diseases and obtaining a better understanding of the risks of transmission of tick-borne diseases via blood transfusion. This one investigation, however, tapped all available epidemiological resources in Iowa for its duration. It illustrates how outbreaks within an individual state can quickly become a challenge at the national level as well.

To ensure that state-level responses to outbreaks of illness are adequate, appropriate, timely, and efficient, surveillance systems for diseases of public health importance must be in place. There need to be adequate resources at the local, state, national, and, occasionally, international levels to respond to and investigate these outbreaks. The needed resources include both adequately trained personnel and resources such as computers, laboratory testing reagents, and environmental monitors. When all of these components come together, the state can be assured that it has the best ability to identify, investigate, and address problems affecting the public's health.

COUNTY-LEVEL PERSPECTIVE ON OUTBREAK INVESTIGATIONS

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The local public health department's role in an outbreak investigation is vital. It is most often the agency charged with maintaining surveillance systems that detects outbreaks and that receives the first call for a response when an outbreak occurs. In most outbreaks, the best opportunity for collection of epidemiological data and laboratory specimens as well as for applicable environmental investigations is in the first few hours to days of the outbreak. These become critical roles of the local health department, for on-site state and federal involvement is often, at a minimum, 1 to 2 days away.

Nevertheless, many barriers to the appropriate accomplishment of this essential public health service exist. Detection and reporting systems remain inadequate in many locales. Many local public health agencies cover small jurisdictions (often jurisdictions with populations under 15,000 to 20,000) and are staffed by a nurse, a sanitarian, a clerk, and a part-time health officer. Thus, a limited number of staff members are available for outbreak investigations because they meanwhile are needed to maintain other critical functions. In addition, it is difficult to develop and maintain the skills required to conduct an investigation given the infrequency of outbreaks' occurrence. Finally, a low administrative priority is often given to outbreak investigations since little funding or planning is dedicated to what is often a rare and intermittent event.

As a bare minimum, local health officials need basic investigational skills in questionnaire design, interviewing techniques, and collection of environmental and clinical specimens. They need computer, media, communications, and coordination skills. Importantly, they need to extend these skills beyond classic foodborne outbreak investigations, because they are increasingly being called to investigate respiratory illnesses in school systems, occupational exposures, nosocomial infections, day care center outbreaks, and so on. Electronic communications systems need to be strengthened so that information about outbreaks can be shared and resources for use during the outbreak can be obtained. Finally, many core-capacity documents, grants, and so on, explicitly define system expectations to the state level only (or combine the expectations for the state and local levels). There is a need to better define expectations about local health department capacities in outbreak investigations.

In sum, local health departments, which are often the first to be called when an outbreak occurs, are often the least equipped to respond. Current inadequacies can be overcome with the assistance and guidance of state and federal agencies and with enhanced collaborations with local agencies. General principles

that should be kept in mind when developing solutions to these issues include the following: (1) Local health departments want to and must remain involved with outbreaks in their jurisdictions. In most, the legal authority for outbreak investigations rests at the local level. (2) Training must be designed to maintain as well as develop these skills, and training must be long-distance accessible. (3) Most local health departments already have working relationships with states (although they may be administratively autonomous). (4) Local health department staff members are open to guidance, direction, and development of new skills but want clear expectations and adequate resources to accomplish them. (5) Building and maintaining the local capacity to detect and respond to an outbreak can dramatically strengthen the public health system's ability to respond to larger epidemics (e.g., a flu pandemic or a bioterrorist attack).

PERSPECTIVES OF PHYSICIANS' COMMUNITY

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Historically, clinicians have played a central role in outbreak investigations and surveillance. Long before the causative agents for infectious disease were known, the observations of medical practitioners served to alert the community to unusual occurrences. Even after the etiologies of infectious diseases have been unraveled and laboratory tests made available, clinicians still play an essential role in providing cases for study and assisting in some epidemiological investigations. Often, however, physicians are not sure when and where to report suspicious cases of disease, are unaware of the need to collect and forward specimens for laboratory analysis, and may not be educated regarding the criteria used to launch a public health investigation. Often, there is lack a of communication among public health agencies and community physicians.

To bring these two sectors together, a number of obstacles need to be overcome, including addressing the historical biases that each group holds about the other, improving communications channels, providing public health offices with the financial resources they need to establish and maintain professional working relationships with the physician community, and educating physicians about the need to interact with public health agencies.

In 1995 CDC announced the Cooperative Agreement Program for Provider-Based Emerging Infections Sentinel Networks in support of an approach that aims to overcome some of the obstacles that impede practitioner involvement in the epidemiological investigation process. The program had its origin in a CDC plan that addressed emerging infectious disease threats; listed under a disease surveillance goal was the aim of establishing two physician-based sentinel surveillance networks to detect and monitor emerging infectious diseases. In 1995

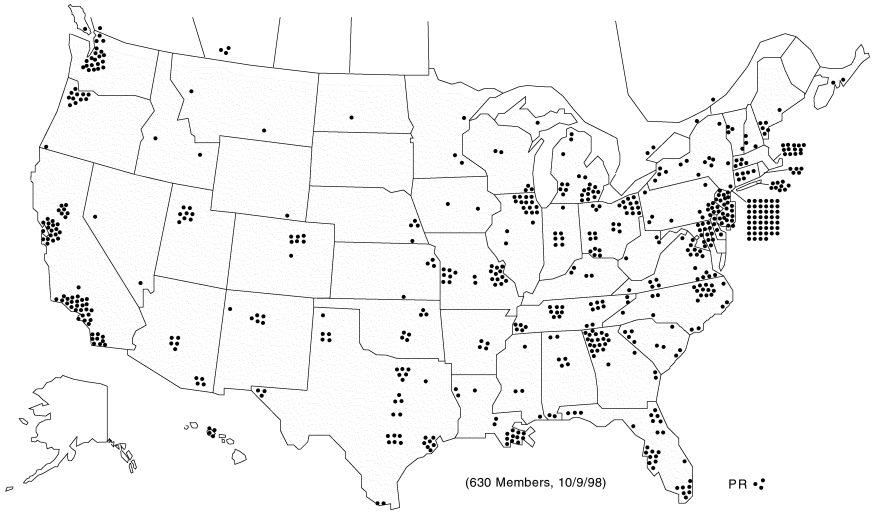

FIGURE 2-1. Geographical distribution of Emerging Infections Network members. Source: Infectious Diseases Society of America, 1998. SOURCE: IDSA Emerging Infections Network, unpublished data.

CDC made awards to (1) the Infectious Diseases Society of America (IDSA), which has 4,700 active members, half of whom are clinical consultants in infectious diseases; (2) EMERGEncy ID NET, a group of academic emergency department physicians; and (3) GeoSentinel (funded in 1996), a group of travel medicine physicians, including some outside the United States, who joined together to report on phenomena related to emerging infectious diseases.

In 1996, the IDSA created the Emerging Infections Network (EIN), which now has more than 700 active members. The strength of EIN lies in its members, who have trained in internal medicine or pediatrics, have completed 2 or more years of subspecialty training in infectious diseases, and serve a varied patient population. EIN members are geographically dispersed and communicate regularly with clinical microbiologists and pharmacists, who help them determine which antibiotics are being used in health care facilities and why (see Figure 2-1).

EIN aims to (1) detect unusual clinical events (2) assist in the identification of possible cases and outbreaks being investigated by CDC and other public health authorities, (3) acquire knowledge about the use of diagnostic tests for specific syndromes in different parts of the country and provide preliminary estimates about morbidity and mortality, (4) collaborate in research with CDC and other public health agencies, and (5) educate and communicate with health care professionals through periodic and ongoing requests for information on a

specific topic. Sometimes EIN makes urgent queries and requests assistance with outbreak investigations, for example, by requesting a 24-hour response on experiences with febrile reactions after once-a-day gentamicin use related to possible endotoxin contamination. When appropriate, EIN sends its initial observations to CDC and to state health departments. It also sends preliminary reports back to its members within a month of issuing the query. Results of queries are published on the World Wide Web (http://www.idsociety.org).

PUBLIC HEALTH PRACTICE AND THE ROLE OF ACADEMIC PUBLIC HEALTH*

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Academic public health institutions are a vital component of the global response to emerging infections. The roles that these institutions play flow directly from their core missions of education, research, and public health practice.

Academic public health institutions maintain primary responsibility for producing a public health workforce that is skilled in responding to emerging infections. This requires (1) fostering an awareness of emerging infections and their public health importance among students in schools of public health, (2) training students in the most advanced concepts and methods for disease surveillance and epidemiological investigation, and (3) ensuring student exposure to and understanding of real-world issues in the prevention, detection, treatment, and control of emerging infections through targeted field experiences and collaboration with public health organizations.

Academic institutions must also assume a primary role in keeping practicing health professionals informed of new knowledge, practices, and technologies that can be used to respond to emerging infections. Schools must capitalize on new technologies in continuing education, distance learning, and executive training that make use of the Internet, wide-area computer networks, and satellite communications. To be effective, these activities must be carried out in close partnership with national, state, and local public health organizations.

Academic public health institutions play central roles in strengthening and expanding the scientific base to identify and respond to emerging infections. This is done through laboratory research, in partnership with researchers in the basic medical sciences, especially microbiology, to develop an understanding of the basic biology of emerging pathogens. Epidemiological research identifies emerging infections in populations to discover the mechanisms of transmission, with the eventual goal being to develop interventions for the prevention, detec-

*Delivered in absentia.

tion, treatment, and control of the infections. This area of research includes the development of new surveillance methods and the use of biostatistical models in predicting disease progression and transmission.

Clinical research further elucidates the clinical practices and technologies that are most effective in preventing, diagnosing, and treating emerging infections. Primarily academic medical schools lead these efforts, often with close collaboration from epidemiologists and biostatisticians in schools of public health.

Behavioral research interprets the roles of human decision making and interactions in the prevention, treatment, and control of emerging infections. Academic public health institutions can bring together the concepts and methods from a variety of behavioral science disciplines—including psychology, sociology, economics, demography, and geography—and apply them to the study of emerging infections.

Health services research, operations research, and program evaluations identify the most effective ways of communicating information, exchanging data, and coordinating efforts in disease prevention, treatment, and control across organizations. This research is critically important as the health system grows more complex, with public- and private-sector organizations sharing responsibilities in disease control and prevention.

Public health policy research informs the policy decisions faced by national, state, and local public health officials in addressing emerging infections. This research can help to answer questions about the public benefits and risks of policies, such as those affecting the privatization of laboratory services, the reporting requirements for public- and private-sector health care providers, and the privacy and confidentiality concerns of patient health and health care information.

It is imperative that academic public health institutions carry out all these research activities in close collaboration with academic medical institutions and that both entities share the knowledge and expertise in emerging infections that each brings to bear. For example, epidemiologists in schools of public health must work closely with colleagues in medical school divisions of infectious disease to elucidate biological pathways and transmission mechanisms.

Academic public health institutions also have important roles to play in providing technical assistance, advice, and consultation to the organizations involved in responding to emerging infections. These activities ensure that findings from scientific research are disseminated, adopted, and implemented within these organizations. Key activities include the following:

- assisting in the design and operation of governmental surveillance and early-warning systems,
- coordinating surveillance and reporting systems across governmental boundaries,
- supporting the adoption and use of new surveillance techniques,

- assessing the preparedness of health care providers to identify and report on emerging infections at the local level, and
- advising organizations on how best to respond to changes in the organization and to changes in the financing of health services and the effects of these changes on disease surveillance capacities.

Traditionally, schools of public health have worked most extensively with state and local health departments, and the entities are natural partners in public health education, research, and practice. A much broader array of organizations is now involved in the practice of public health generally and in the response to emerging infections more specifically. Academic institutions must find ways in which they can work more effectively with this broader array of organizations, including commercial laboratories, managed care plans, hospitals, and private physicians.

3

Surveillance

OVERVIEW

Infectious disease surveillance is the first link in the response to emerging infections. The United States spent $74.5 million in 1992 for all infectious disease surveillance activities (Osterholm et al., 1993). Although the total amount of surveillance has increased in recent years, there have been dramatic cutbacks in surveillance for human immunodeficiency virus (HIV) infection, tuberculosis, and vaccine-preventable diseases (Michael Osterholm, state epidemiologist and chief, Minnesota Department of Health, personal communication, November 1998).

Infectious disease surveillance concurrently involves the health care delivery system, the public health laboratory, and epidemiologists. Each of these sectors contributes to the four basic components of surveillance, which are (1) collection, (2) analysis, (3) dissemination, and (4) response. Collection and analysis can be conducted at the local, state, federal, or international level by public agencies as well as by private industry. Dissemination and response are specific public health activities. Thus, disease surveillance is the ongoing, systematic collection and analysis, interpretation, and feedback of outcome-specific data. As such, surveillance may monitor cases of disease reported by clinicians or identified in laboratories, or it may monitor changes in practice or other behaviors of public health importance.

Relevant activities at the federal level include assessment of surveillance programs, funding of state activities, provision of services, and nationwide disease surveillance. At the state level, health departments establish the systems by which infection and disease are reported, data are gathered, and prevention is initiated. State and local health departments also play a vital role in educating

physicians about the need to report and gather appropriate data. In the private sector, pharmaceutical companies and organizations that provide diagnostic services play a critical role in conducting large-scale surveillance for drug and vaccine development and in providing clinical data for retrospective and prospective studies.

Surveillance information is derived from many sources, and approaches to surveillance may vary depending on the kind of information that is needed and the resources that are available. Surveillance information is used in a variety of ways: to identify cases for investigation, to estimate magnitude of disease, to detect outbreaks, to evaluate response and prevention measures, to monitor changes in infectious agents, to facilitate research, and to measure the impacts of changes in health care practices.

Although there are common uses of surveillance data at the local, state, and federal levels, emphases vary. For example, individual case investigation is critical at the local and state levels but less critical at the federal level, unless a multijurisdictional disease outbreak occurs. Evaluation of larger-scale prevention and control measures—for example, the impact of new vaccines—is a high priority at the federal level. A national surveillance plan should take into account this diversity in the uses of data, approaches, and emphases at different government levels.

GAO REPORT ON PUBLIC HEALTH SURVEILLANCE OF EMERGING INFECTIOUS DISEASES

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Helene Toiv, M.P.A., *Assistant Director,*
Health, Education, and Human Services Division,
U.S. General Accounting Office

A number of changes in the health care system—such as consolidations and managed care—combined with recent outbreaks of infectious diseases thought to be under control have led policy makers to evaluate, among other things, the functioning of public health and clinical laboratories. One such assessment was conducted by the U.S. General Accounting Office (GAO), a research agency of the U.S. Congress.

The GAO focused its effort on four tasks: (1) to describe the roles of different categories of private and public laboratories; (2) to gather information on the extent to which state surveillance programs and state public health laboratories contribute to the surveillance of six specific diseases;[1] (3) to define the problems

[1]The six specific diseases were tuberculosis, shigella toxin producing *Escherichia coli* infections, pertussis, cryptosporidiosis, hepatitis C, and penicillin-resistant streptococcal pneumonia. The diseases were chosen to represent various modes of transmission (foodborne, waterborne, and airborne) and different levels of antimicrobial resistance.

faced by public health officials, particularly at the state level, in gathering and using laboratory-generated information; and (4) to report on the role of the Centers for Disease Control and Prevention (CDC), particularly the kind of assistance it provides to the states. To conduct the assessment, GAO surveyed all state public health laboratory directors and all state epidemiologists and conducted case studies in Oregon, Kentucky, and New York.

GAO's survey gathered information about the kinds of tests that the state public health laboratories performed in connection with the selected diseases, whether the state epidemiology program includes the six diseases in its surveillance program, and reporting requirements. Data were also collected on resources, both financial and human, and electronic communications. State officials were also asked about the assistance they received from CDC (see Box 3-1).[2] Summary findings from the survey are found in Appendix C.

EMERGING INFECTIONS PROGRAM COOPERATIVE AGREEMENT

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Following publication of the 1992 Institute of Medicine (IOM) report *Emerging Infections: Microbial Threats to Health in the United States* (IOM, 1992), CDC developed a plan to address emerging infections. It was released in April 1994, and was recently revised and updated. Since then, progress has been made in implementing this plan. The plan has the following four goals: (1) surveillance and response, (2) applied research, (3) infrastructure and training, and (4) prevention and control. In addition, among other activities, CDC sponsors the *Emerging Infectious Diseases Journal*, the CDC Association of Public Health Laboratory Directors, and public health laboratory fellowships, and provides support for World Health Organization collaborating centers.

[2]Data may be found in the GAO report issued after the workshop was held, titled, *Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance*, (GAO/HEHS-99-26, February 5, 1999). A copy of this report may be obtained by calling (202) 512-6000, faxing a request to (202) 512-6061, or through the GAO website at http://www.gao.gov (select GAO Reports and Testimony, select FY 1999 from the Annual Indexes, select the Authoring Division index, select Health, Education, and Human Services, choose HEHS-99-26).

BOX 3-1. GAO Report HEHS-99-26
Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance

Surveillance and testing for vital emerging infections are not comprehensive in all states, thereby leaving gaps in the nation's infectious diseases surveillance network. To assess the contribution of laboratories to the surveillance network, the GAO conducted a survey from December 1997 through December 1998, of the directors of all state public health laboratories and infectious diseases epidemiology programs that report disease-related information directly to CDC. One of the findings reported that many state laboratory directors and epidemiologists felt that inadequate staffing and information-sharing problems hinder their ability to generate and use laboratory data for surveillance activities. Because public health officials have not agreed on a definition outlining the minimum capabilities that state and local health departments need to conduct infectious disease surveillance, this lack of consensus has ultimately made it difficult for policy makers to assess the adequacy of existing resources or to determine where investments are mostly needed. The GAO has therefore recommended that the Directors of CDC lead an effort to help federal, state, and local public health officials create consensus on the core capabilities needed at each level of government.

CDC's emerging infectious disease surveillance strategy makes an effort to take into account the diversity of needs and approaches through three complementary cooperative agreement programs: (1) the Epidemiology and Laboratory Capacity (ELC) program, (2) the Emerging Infections Program (EIP) network, and (3) provider-based sentinel networks. (See Figure 3-1 for a map of program locations; for more information, see the CDC website: www.cdc.gov.)

The purpose of the ELC program is to assist state and large local public health agencies in strengthening their basic epidemiological and laboratory capacities. It currently covers 30 jurisdictions, with full implementation of ELCs expected by the year 2002. (Essentially there would be ELCs in 63 jurisdictions, including states, large cities, and territories.) Health departments use these funds in a variety of ways, although the amount of total resources available is small relative to the needs. The ELC program has highlighted the challenge to define more clearly the required core laboratory and epidemiological capacities for the local, state, regional, and national levels and for various program areas, such as infectious diseases, foodborne diseases, and bioterrorism. A variety of activities are pursued in ELC program cooperative agreements, including enhanced information exchanges, training, education, and laboratory capacity, particularly including Pulsed Field Gel Electrophoresis (PFGE). Some states have been emphasizing collaborations with local health departments.

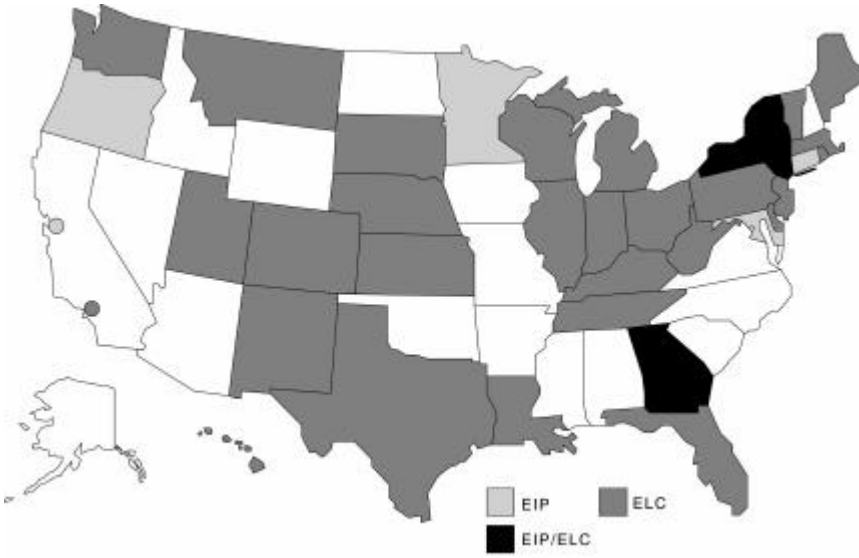

FIGURE 3-1. Map of Emerging Infections Programs (EIP) and Epidemiology and Epidemiology and Laboratory Capacity (ELC) Cooperative Agreements. SOURCE: CDC, 1998.

Eight EIP network sites distribute their activities among a variety of emerging infections program foci, including activities that address foodborne diseases (FoodNet); a family of project activities that involve invasive bacterial diseases (Active Bacterial Core surveillance, or ABCs); and surveillance for unexplained deaths and critical illnesses. Other activities include programs on judicious antibiotic use, surveillance for hepatitis, and enhancing the rate of immunization against pneumococcal infection. Full implementation of EIPs (in 10 jurisdictions total) is expected by the year 2002.

Population-based surveillance information plays a critical role across the EIP network. For example, all the sites perform active laboratory-based surveillance for invasive pneumococcal disease. Cases are defined by the isolation of *Streptococcus pneumoniae* from normally sterile sites, usually blood or cerebrospinal fluid. Such cases are sought actively by regular contact with the laboratories. Efforts are made to ensure that the data are comparable across sites and that there is essentially complete case ascertainment. This approach requires considerable effort and coordination among the sites and at CDC.

During 1995 and 1996 the incidence of invasive pneumococcal disease varied substantially across the sites, from 14.2/100,000 population in Toronto to more than 30/100,000 population in California and Georgia (see Figure 3-2). A convenience sample of pneumococcal isolates from assorted laboratories could

not be used to characterize incidence in this way or demonstrate with confidence geographic variations in incidence. Rates of invasive pneumococcal disease vary considerably by age and race, which, along with the geographic distribution of underlying diseases like HIV infection that predispose individuals to pneumococcal disease, account for the geographic variations in the incidence of invasive pneumococcal disease.

Active surveillance entails the collection of isolates, as well as case reports. Through such means of active surveillance, isolates have been tested at a common laboratory by reliable methods to measure penicillin susceptibility. The proportion of penicillin-resistant and -intermediate resistant isolates varies by site (see Figure 3-3). The distribution of penicillin resistance and intermediate resistance also varies by age, with the highest proportion of resistant and intermediate isolates found in young children. In some areas the distribution varies by race with whites having a higher proportion of infection with resistant isolates than blacks (though blacks have a higher overall incidence of pneumococcal disease).

Another example of population-based surveillance in the EIPs is a set of activities called FoodNet. FoodNet is designed to determine and monitor the burden of foodborne diseases and improve understanding of the proportion of foodborne diseases attributable to various pathogens. Active laboratory-based surveillance along with laboratory, physician, and population surveys are used

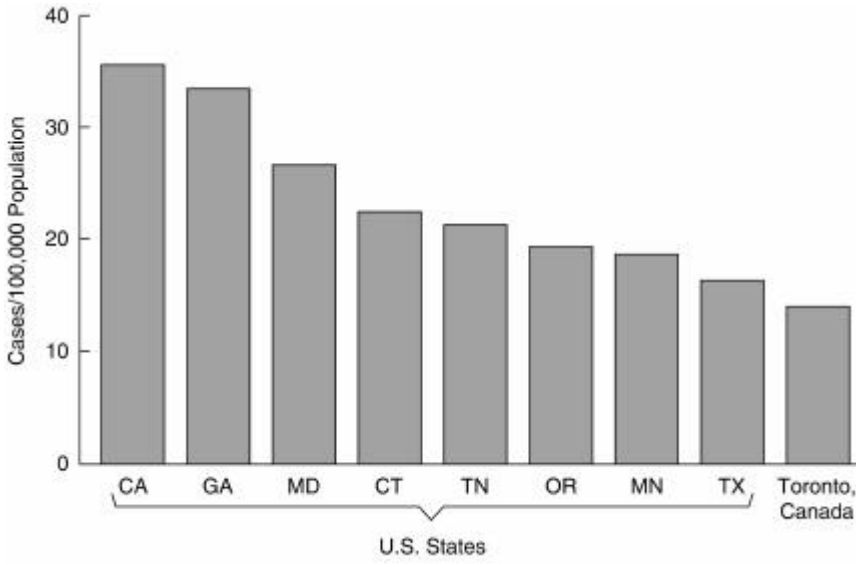

FIGURE 3-2 Incidence of *Streptococcus pneumoniae* disease, by state, July 1995 to June 1996. SOURCE: Cetron et al., 1997.

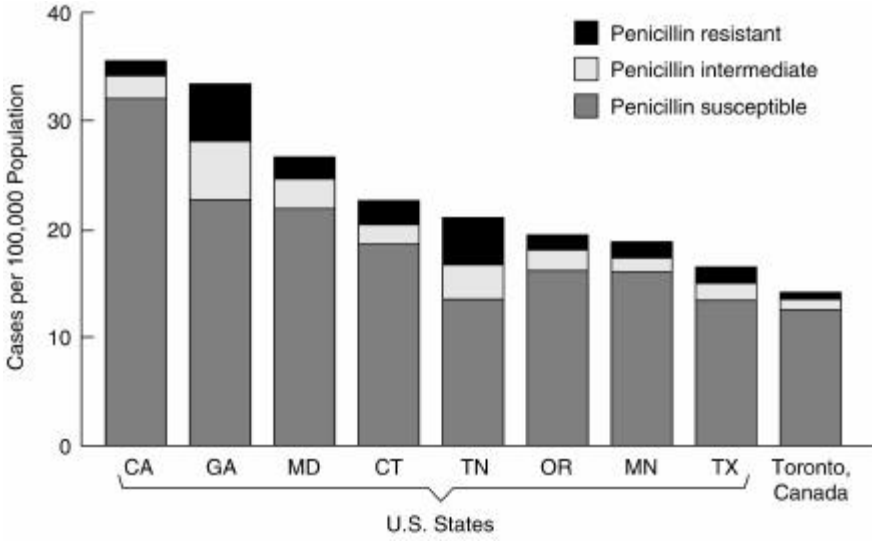

FIGURE 3-3 Incidence of invasive *Streptococcus pneumoniae* disease by geographic area and penicillin susceptibility. SOURCE: Cetron et al., 1997.

together to obtain estimates of the foodborne disease burden. For example, *Campylobacter* is the most common of the bacterial foodborne pathogens in FoodNet in this surveillance, followed by *Salmonella* and *Shigella.*

Population-based surveillance reveals seasonal, geographic, and demographic variations in foodborne diseases. For example, in the San Francisco Bay area, where the rates of foodborne illnesses caused by *Campylobacte*r are the highest, rates of illness are much higher among Latino and Asian children than among other groups. This has prompted a case-control study of the risk factors for foodborne *Campylobacter* infections[3] in Latino and Chinese-American children in the California EIP.

Surveillance for *Campylobacter* infections has also enabled a focused look at quinolone resistance in Minnesota. The proportion of *C. jejuni* isolates resistant to nalidixic acid increased over time. These infections occur in persons with a history of foreign travel, reflecting foreign exposure to resistant organisms. Increasingly, however, resistance is being observed among domestically acquired cases. This provides another example of how population-based surveillance data are enhanced by a focused look at an important public health phenomenon.

[3]Infections refer to the entry and development of an infectious agent in the body of a person or animal. In an apparent, "manifest" infection, the infected person outwardly appears to be sick. In an unapparent infection, there is no outward sign that an infectious agent has entered the person at all. Infection should not be confused with disease.

The highest incidence of *Escherichia coli* O157:H7 infection has also occurred in Minnesota. However, an EIP network-wide survey on physician knowledge of laboratory practices showed that physicians in Minnesota were more knowledgeable about whether their laboratories routinely cultured clinical specimens for *E. coli* O157:H7. They were also more likely than physicians at other sites to have actually obtained a sample for *E. coli* O157:H7 culture from their last patient with bloody diarrhea, suggesting that at least some of this apparent difference in incidence may be attributable to variations in practice.

Recent changes in the epidemiology of bacterial meningitis in the United States have resulted from the decline to very low levels of *Haemophilus influenzae* type b (Hib) due to the licensing and use of effective conjugate vaccines. At the same time, however, Group B streptococcal infections have emerged as an important cause of neonatal meningitis and sepsis in the United States;they are responsible for an estimated 7,500 cases of sepsis[4] and meningitis[5] annually among newborns with direct costs of $300 million. Accordingly, the EIP network has been using active, population-based surveillance to track the incidence of this disease, and also to gauge the uptake and impact of Group B streptococcal infection prevention policies.

In 1996, CDC, together with the Academy of Pediatrics and the College of Obstetricians and Gynecologists, developed consensus guidelines for the prevention of Group B streptococcal disease. These guidelines included late prenatal screening to identify Group B streptococcus carriers, intrapartum prophylaxis of preterm deliveries and carriers, and empiric prophylaxis based on risk factors for Group B streptococcus disease at labor. Surveillance data later showed a decline in the incidence of neonatal Group B streptococcal infection, but only in the incidence of disease with onset early in life. This is essentially what would be predicted if preventive policies were in place (see Figure 3-4).

Additional data indicate that hospitals with no Group B streptococcal prevention policy had little or no decrease in the mean number of cases of Group B streptococcus infection between 1996 and 1997, but hospitals that adopted or revised a Group B streptococcus prevention policy in 1996 saw a significant decline in the number of early onset cases of Group B streptococcal infection (see Table 3-1).

In conclusion, the EIP Network has been a valuable component in the implementation of CDC's plan to address emerging infections by emphasizing population-based active surveillance and collaboration among CDC and partners in the public health and academic communities.

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[4]Sepsis is the presence of pathogenic microorganisms or their toxins in blood or other tissues.

[5]Meningitis is an inflammation of the membranes surronding the brain and spinal cord. People sometimes refer to it as spinal meningitis. Meningitis is usually caused by a viral or bacterial infection.

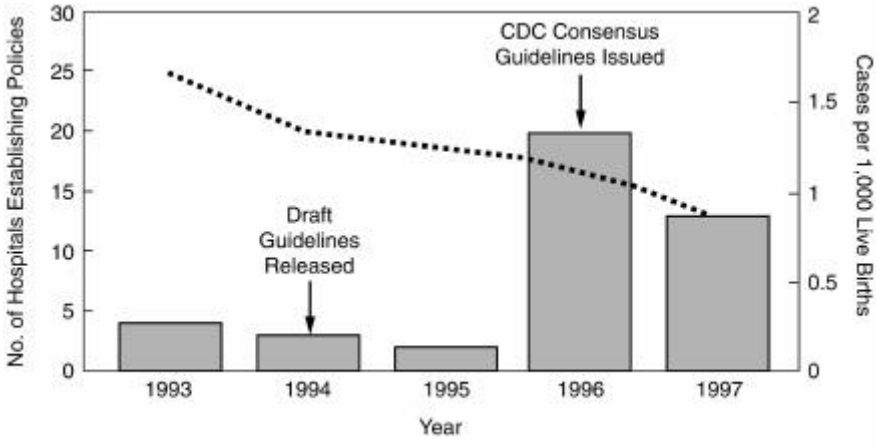

FIGURE 3-4 Number of hospitals in California, Georgia, Maryland, and Tennessee establishing Group B streptococcus prevention policies and the incidence of early-onset Group B streptococcal disease by year, based on active surveillance. SOURCE: Adapted from Rosenstein et al., 1997.

LARGE NATIONAL COMMERCIAL LABORATORIES

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Private companies, such as SmithKline Beecham Pharmaceuticals, have an interest in antimicrobial agents and vaccines. To pursue these interests, antimicrobial susceptibility surveillance studies are conducted to determine the percentage of organisms that are susceptible to different antimicrobial agents.

Large commercial laboratories have several reasons to pursue surveillance: (1) quality assurance, (2) as a service to customers (e.g., for respiratory infections, data on susceptibility could affect empiric therapy) (3) compliance with federal regulatory agencies through the provision of data on reportable diseases, (4) as a service to current public health, and (5) product development.

In 1993, the FDA requested that pharmaceutical companies gather and submit in vitro susceptibility data for organisms that were listed on the product information label (package insert available for prescription drugs). As a result, pharmaceutical companies have an interest in gathering in vitro susceptibility data on organisms. In addition, the pharmaceutical industry conducts antimicrobial surveillance to demonstrate the activity of a drug in comparison with those of other agents.

Such surveillance studies usually include isolates from community-acquired or hospital-based infections. These studies are conducted to track rates of resis-

tance, in part to ensure that the drug maintains its activity so that the organism can remain on the product labeling.

For drugs that are in development, surveillance is also critical as an adjunct to or in support of clinical trials. Some clinical studies are required to establish that a drug has efficacy against resistant pathogens, which is difficult if the rates of resistance are low. Moreover, because of the study design, a majority of isolates from the patients in the clinical study may not be highly resistant, requiring supplemental in vitro studies.

Traditional surveillance entails large-scale studies over a wide geographic region to collect isolates for susceptibility testing. Targeted surveillance involves searching for geographic areas where isolates are resistant. This type of surveillance is useful when developing novel antimicrobial agents. Molecular or genetic-based studies are also used for surveillance. Finally, existing databases, such as those created through routine susceptibility testing, provide another opportunity for surveillance.

The SmithKline Beecham Clinical Laboratories (now Quest Laboratories) are among the largest clinical laboratories in the United States, with more than 80,000 physicians, hospitals, and corporate clients and more than 100 million tests processed annually. One of its efforts is Project Beta-Alert, a *Haemophilus* study that aims to determine the percentage of beta-lactamase-producing *Haemophilus influenzae* strains among the *H. influenzae* isolates sent to the large commercial reference laboratory. The project includes isolates from most states. As part of the routine daily work, a technologist isolates the organism, identifies it as *H. influenzae*, and performs the beta-lactamase test. The data can be tracked to a zip code. Data from 1997, sorted by specimen source, patient age, month of collection, laboratory site, state, and zip code, suggest that for empiric therapy, 3 in 10 patients require treatment with a drug resistant to beta lactamase activity. Data collected from 1993 to 1997 for 44,691 *Haemophilus* isolates showed that 35 percent produced a beta-

TABLE 3-1, Early-Onset Group B Streptococcus (GBS) in Hospitals with and Without Prevention Policies in 1996

GBS Policy in 1996	No. of Hospitals	Mean No. of Births, 1996	Mean No. of GBS Cases		*p* Value
			1996	1997	
None	66	1,720	1.32	1.09	0.26
Any new or revised policy	45	1,672	1.29	0.58	0.006

NOTE: Hospitals with policies had a significant decline in cases.

SOURCE: Adapted from Factor et al., in press.

lactamase, with the highest percentage of isolates being from children under age 6. Another study conducted in 1997 and 1998 involved collection of 2,000 isolates each of *Streptococcus pneumoniae* and *H. influenzae*. Isolates were collected from SmithKline Beecham laboratory sites in all regions of the United States and were sent to a central laboratory for testing. For *S. pneumoniae*, the highest rate of penicillin resistance was found among isolates in samples from the south-central and southeast regions of the United States. Macrolide resistance was also highest among isolates in samples from the south central and southeast regions of the United States. The surveillance data also showed rates of penicillin resistance in *S. pneumoniae* by site of infection, with the ear and sinus isolates having the highest rates of penicillin resistance. Data on age distribution revealed that the vast majority of the drug-resistant *S. pneumoniae* and *Haemophilus* isolates were found in young children less than 2 years of age.

Examples of other large surveillance projects in the planning stage include a pneumococcal surveillance project, the development of a national database on gram-positive and gram-negative organisms, and surveillance for drug resistance among *Mycobacterium tuberculosis* strains. Studies that attempt to correlate antimicrobial agent use with antimicrobial agent resistance, a relationship that is difficult to establish, are also being considered.

Some companies provide in vitro data from an on-line surveillance network, which connects hospitals with company computers on a nightly basis. Data on all the organism identifications and the results of susceptibility testing are collected. However, because samples come from many states and states vary in their reporting practices, data collection can be arduous. In addition, a networked system between the private and public sectors requires a certain level of data standardization. This type of routine data collection is an invaluable resource in retrospective analyses for surveillance purposes.

Any large-scale private surveillance effort must guard against violation of patient privacy as well as breach of proprietary concerns. Because diseases cross borders, such commercial work must also contend with international issues. Moreover, large-scale surveillance is expensive and profit margins are slim for commercial clinical laboratories. Given these limitations, it will be increasingly important for the public and private sectors to arrange collaborative surveillance projects on matters of widespread public health consequence.

ROLE OF THE PUBLIC-SECTOR LABORATORY AT THE NATIONAL LEVEL

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Centers for Disease Control and Prevention

In 1988, IOM defined public health as what society does collectively to ensure the conditions in which people can be healthy (IOM, 1988). The core func-

tions of public health are assessment, policy development, and assurance. Activities performed by the public health sector include the following:

- population-based disease surveillance;
- epidemiological investigations;
- environmental assessments of food, water, and vectors;
- ensuring the quality of public-and private-sector laboratory testing;
- tracking incipient trends;
- conducting outbreak investigations;
- tracking the distribution and the migration of noteworthy pathogens; and
- monitoring the effectiveness of prevention programs.

CDC laboratories make a unique contribution to reference diagnostic or confirmatory testing. CDC also plays a pivotal role in gathering, collating, and analyzing data from multiple sources. For example, reports of deaths due to pneumonia and influenza come to CDC from many sources: state health departments, physicians, and a World Health Organization network comprising 110 different laboratories, in 83 different countries, that obtain isolates and use reagents and materials provided by CDC to determine the influenza virus type. CDC can further subtype isolates submitted to it by using molecular sequencing. All these efforts ensure relevance of the influenza vaccines produced every year.

Another example of a key role of a national laboratory, such as CDC's National Center for Infectious Diseases, is in the characterization of various measles virus isolates to determine if prevention efforts have stopped the indigenous transmission of measles. To conduct this work, isolates were obtained throughout the world and were then sequenced for determination of their genotypes. It was found that certain measles viruses are peculiar to certain areas of the world and that transmission is indigenous in those countries. The data also showed that a measles vaccination program had been effective in interrupting transmission of the measles virus in the United States and that the existing vaccine offered protection against those isolates reported from outside the United States.

CDC and other laboratories also serve as international reference laboratories for determination of whether polio virus types 1, 2, and 3 are being transmitted and whether polio virus infections are caused by wild-type strains or breakthroughs of the attenuated vaccine strain. Such information is crucial in immunization efforts.

Despite the strengths of the public-sector national laboratories, there is a need for collaboration with private-sector facilities in the standardization of databases and the evaluation of reagents and techniques. Such collaborations will be particularly important because cost-containment efforts and changes in the ways in which health care is administered may compromise disease surveillance efforts. For example, under managed care, there is a disincentive to collect isolates and specimens for cultures on which laboratory surveillance is based. In

certain instances, the commercial laboratory system has supported the state public health laboratories when high-volume testing has been needed for tests for rare and unusual diseases. In contrast, public health laboratories are more suited to performing specialized testing.

In the absence of a well-defined national laboratory system, more strategic planning is needed. This would entail, for example, defining the surveillance and information needs for specific diseases, the type of testing needed, the materials and specimens required, the roles of the public and private sectors, and the referral systems and core capabilities, as well as standardizing methods and databases.

ROLE OF THE PUBLIC-SECTOR LABORATORY AT THE STATE LEVEL

Mary Gilchrist, Ph.D.
Director, University of Iowa Hygienic Laboratory

Most state public health laboratories were instituted in the early part of the 20th century, when they were nearly the sole source of expertise and training in public health and when a microscope might have been the primary tool available for diagnosis of a disease. By mid-century there was a decline in the rate of infectious diseases and a rise in local laboratory expertise, which led to more focus at the state level on diseases of traditional public health importance such as tuberculosis, syphilis, and rabies and on specialized reference bacteriology and virology.

By the 1970s another type of state public health facility, the combined or consolidated laboratory, emerged when the U.S Environmental Protection Agency was instituted and some public health laboratories expanded to include environmental testing. A third type of laboratory, the consolidated laboratory, performs still other services for the state in the areas of agriculture, forensics, and some newborn screening.

By the mid-1990s, with the inception of the emerging infections program, CDC's new cooperative agreements with states created new opportunities and challenges for state laboratories. They began expanded activities such as typing of *Mycobacterium tuberculosis*, *Escherichia coli* O157, and *Salmonella* isolates and characterization of antibiotic resistance. New molecular techniques such as these have established critical new roles for public health laboratories.

Most public health laboratories have routine surveillance programs for infectious agents of significance in their regions. Outbreaks are then detected earlier and are defined more clearly.

An example of an active state surveillance program is Iowa's influenza virus surveillance activities. At the state laboratory the influenza virus is isolated, identified, and typed before being sent to CDC as part of the World Health Organization surveillance system that tracks disease and predicts vaccine needs.

The state laboratory automatically posts nightly on the Internet (http://www.uhl.uiowa.edu) all of the influenza virus isolates in its database. Thus, real-time data on the geographic incidence of various influenza virus types and the number of isolates that have been detected in each of the state's regions throughout the winter season are available. In the future, the system will offer quicker detection of more viral agents. It will also provide hypertext links to information on vaccines and antiviral therapies. Thus, if a clinician wants to know whether the current vaccine is effective against a given circulating strain, a query to the website will provide that information.

The public health laboratory in Iowa also conducts vector-borne disease surveillance. For example, it monitors sentinel chicken flocks for the presence of antibodies to arboviruses and examines pools of mosquitoes for the presence of arboviruses, enabling cities and counties to control mosquitoes before encephalitis[6] viruses cause a substantial risk to humans. Surveillance for the emergence of tick-borne infections is also conducted in Iowa. Deer hunters send in samples of deer blood on filter paper for studies of the distribution of antibodies against the Lyme disease spirochete and the agents of ehrlichiosis. Surveillance for vector-borne diseases has shown how these pathogens are emerging in Iowa along the Mississippi River through animals that are migrating up the river valleys. As a result, public health laboratories can alert health care practitioners about the prevalence of new infectious agents in Iowa.

In collaboration with the University of Iowa, the state Hygienic Laboratory conducts an antibiotic resistance surveillance program, looking for organisms that cause invasive diseases: enterococci, *Streptococcus pneumoniae*, methicillin-resistant *Staphylococcus aureus*, vancomycin-intermediate or -resistant staphylococci, and Group A streptococci. The University of Iowa conducts the susceptibility testing, and the Hygienic Laboratory codes and serotypes the isolates. The data are available on the Internet so a health care practitioner can check on the prevalence of resistance in the area of the state where the patient resides.

Iowa is also planning a program that will detect infectious agents that could be released as a result of terrorism. Because such an attack is likely to result in the dispersal of infection in isolated settings throughout the country, the state public health facility is likely to be involved. In the various scenarios contemplated the need for adequate reporting and recognition by the attending physician are paramount for surveillance. For example, if a physician does not remember that anthrax is caused by a *Bacillus* species and does not notice that the laboratory reported it as a bacterial contaminant, he or she might not immediately attribute a death to anthrax. The cause of the disease might not be detected until later, when reports of a mysterious illness surface around the country. In some cases, the laboratory might presume that the isolate is a member of the

[6]Encephalitis is an acute inflammatory disease of the brain due to direct viral invasion or to hypersensitivity initiated by a virus or other foreign protein.

patient's normal flora and it is not until the isolate is referred to a central reference laboratory, possibly 2 weeks later, that the agent released by bioterrorists would be identified.

Identifying and reporting such agents are shared responsibilities of a national laboratory network of state facilities and local laboratories. In this regard, the Internet will serve as an invaluable tool for the sharing of information. In addition, what is needed is rapid communication, combined with algorithms for pathogen and disease identification, protocols for safety, a national laboratory training network, and the ability to detect multi-state outbreaks in real time. The Association of Public Health Laboratories recommends the formation of such a national network. State laboratories, because of their environmental chemical expertise, could augment the network by providing a means of detection of the agents of chemical terrorism. Preparation of state and private laboratories for bioterrorism events will enhance the ability to detect infectious diseases that emerge naturally.

4

Communication, Coordination, and Education and Outreach

OVERVIEW

Agencies charged with the responsibility for conducting infectious disease surveillance and response activities need to have well-established communications systems that can facilitate the timely collection of surveillance data and provide national alerts of disease outbreaks to the appropriate personnel. These communications systems are challenged by the need to share information across state lines and jurisdictions, with federal agencies, and with a variety of local and intrastate groups, including health departments, other state agencies, laboratories, emergency departments, hospitals, physicians, the public, and the media.

COMMUNICATION AND COORDINATION AT THE NATIONAL LEVEL: THE PULSENET MODEL

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Molecular subtyping of pathogenic organisms is an integral part of epidemiological investigations and surveillance. It is used for microbiological confirmation of outbreaks identified by epidemiological investigations, and in case-control studies. Molecular typing helps to define the population that is involved in an outbreak. In the area of foodborne diseases, molecular subtyping

has enabled the linkage of cases with no apparent connection to a single source outbreak.

PulseNet is a national molecular subtyping network for foodborne disease surveillance (http://www.cdc.gov/ncidod/dbmd/pulsenet/pulsenet.htm) that is used as a model for communication and coordination. It is a collaborative, cooperative program among the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture's (USDA's) Food Safety and Inspection Service (FSIS), state and local health departments, and the Association of Public Health Laboratories. It is a network of public health laboratories and food regulatory agency laboratories. The laboratories that participate in the network perform molecular subtyping of bacteria that cause foodborne and diarrheal diseases, and also perform tuberculosis subtyping work using the PulseNet standardized protocol and reference standards. The DNA patterns are analyzed by using standard software programs. Collaborating laboratories then electronically communicate the results to CDC.

Although the project was initiated in 1996 with subtyping for *Escherichia coli* O157:H7, it has since been extended to nontyphoidal *Salmonella*, *Shigella sonnei*, and *Listeria monocytogenes*. Eventually, PulseNet will cover all foodborne pathogenic bacteria.

PulseNet uses pulsed-field gel electrophoresis (PFGE) for molecular subtyping of foodborne pathogens. The rationale for the program is that state health department laboratories have limited resources and it is unrealistic to expect that they would use different typing methods for each type of organism. PulseNet offers the opportunity of coordination for standardized typing of a number of pathogens. The national database of DNA patterns is set up at CDC, which has the responsibility for maintaining and coordinating the database.

At present, there are 38 PulseNet laboratories: 32 state health department laboratories, the Los Angeles County public health laboratory, the New York City public health laboratory, 2 FDA laboratories, 1 USDA laboratory, and a CDC laboratory. Four state health department laboratories serve as area (regional) laboratories: those in Minnesota, Washington, Texas, and Massachusetts. Area laboratories provide PFGE typing assistance to neighboring states that do not yet have the capability to type the organisms involved in outbreaks. Also, area laboratories provide technical assistance and training to neighboring states as needed, and surged capacity when required. Funding comes from the National Food Safety Initiative, CDC's Emerging Infections Program (the FoodNet sites are also PulseNet sites), and state health departments.

PulseNet plays a key role in outbreak investigations. For example, in June 1997, the Colorado State Health Laboratory had just started routine subtyping of *E. coli* O157:H7, and within 2 weeks of instituting this procedure it showed that the isolates from several samples had the same DNA patterns. This discovery resulted in one of the largest recalls of ground beef in U.S. history. An ensuing epidemiological investigation found common source links and also linked a spe-

cific case in Pueblo, Colorado, to frozen hamburger patties that originated from the Hudson Company.

USDA's FSIS isolated *E. coli* O157:H7 from the preformed beef patties obtained from the patient's freezer and performed the subtyping of the meat isolate. The clinical isolates were subtyped at the Colorado State Health Laboratory. Both sets of DNA patterns were electronically transmitted to CDC, where the isolates were immediately confirmed as being identical. The DNA pattern was posted on the PulseNet server, and within 48 hours, information was received on more than 300 isolates, with no matches found, indicating that the outbreak was not occurring nationwide. PulseNet laboratories can communicate with the CDC database via direct access to the CDC server by Internet or high-speed modem and through file transfer protocols and e-mail. The CDC server is also being set up to automatically generate e-mail warnings if two or more laboratories submit the same pattern within a preselected window of time. This is to enable the rapid detection of multistate outbreaks. The patterns for specific isolates that FSIS or FDA has obtained from contaminated food can also be posted on the Internet.

An Internet listserver group provides for two-way communication between PulseNet laboratories and allows participants to exchange information on any aspect of molecular subtyping. In addition, when a laboratory has specific questions or problems about a technique, they are using the listserver to communicate with CDC and others. The listserver is also available to participants so they can post patterns and query others if they have encountered those patterns.

PulseNet has training and quality control and assurance programs that are coordinated by CDC. When a laboratory joins PulseNet, it must send a laboratorian to attend a 5-day workshop at CDC to learn the standard protocols. A yearly update meeting is convened for PulseNet laboratory personnel and a biannual meeting of epidemiologists and laboratory personnel is held to discuss the appropriate use of molecular subtyping in epidemiology. CDC organizes workshops, establishes and maintains DNA pattern databases, tracks subtyping activities at PulseNet laboratories through weekly e-mail feedback, coordinates subtyping work at area laboratories, and coordinates subtyping work for multistate outbreaks. Despite its successes, PulseNet is insufficiently funded and stretched in its ability to subtype every isolate and follow up with appropriate epidemiological investigations due to a lack of trained professionals.

PulseNet provides an expanded capacity for real-time interstate sharing of information on the PFGE of selected bacterial species associated with foodborne diseases. This on-line network and library offers an opportunity for the timely sharing of information that can facilitate the recognition of an outbreak in a way that a national electronic reporting system cannot.

COMMUNICATION AND COORDINATION AT THE STATE LEVEL

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At the state level, communication and coordination in response to emerging infections should be examined from several perspectives. It is necessary to have an understanding of the state public health role in responding to emerging infections and an understanding of associated communication and coordination needs at the state level. It is also important to review how those needs are currently being managed. Finally, it is critical to review the issues that need to be addressed to improve the capacity to respond to emerging infections.

States have the primary statutory authority to conduct surveillance in order to control infectious diseases and detect outbreaks. Each state has its own statutes that empower the commissioner of public health to collect information related to infectious diseases and outbreaks and to communicate that information.. Thus, states have the authority to require certain information to be reported, and physicians and laboratories must cooperate with state agencies and provide the required information. By contrast, CDC does not have direct authority over states to collect information, and it can expect only voluntary cooperation. Correspondingly, most national surveillance data on infectious diseases are provided by states, including any disease suspected of being an emerging infection. Furthermore, CDC cannot assist states in the investigation and control of outbreaks unless it is invited to do so by the state. As a result, national population-based surveillance and response are heavily dependent upon each state's capacities for surveillance and response and the associated communications capacity. States are major communications hubs in the response to any acute emerging infections. The state of Connecticut has one of the original four population-based emerging infection sites funded by CDC.

States need several communications capacities to carry out their responsibilities regarding surveillance for and response to emerging infections. To effectively perform surveillance and communicate the results, timely communication systems are needed. For example, states need to be able to detect cases of *Escherichia coli* O157:H7 infection in a timely fashion in order to identify outbreaks that require a response. Communication systems are therefore necessary to provide timely laboratory reports for outbreak detection or case response, or both, for example, 24-hour reporting from physicians in hospitals. States must also have the capability to transmit information rapidly. For example, when the threat of rabies transmission by raccoons first arrived in the region, the state health department in Connecticut had to inform the medical and animal control communities on how to best respond. Every state must also be prepared to contact physicians in the event of imported cases of plague or Ebola virus infec-

tions. Moreover, states need to be able to share routine surveillance data, for example, on the prevalence of antibiotic resistance.

Whenever an outbreak goes beyond state lines, such as an outbreak of *E. coli* from a widely distributed food product, there is a need for systematic communication with other states and with CDC. Communication with hospitals, emergency departments, physicians, and the media must also be rapid. A coordinated investigation and response increases the ability to determine the cause of an outbreak, avoids duplicative efforts, and allows for a uniform public health response between jurisdictions.

Too often, however, communications systems at the state and local levels are outdated, ad hoc, situational, or underfunded. There has been little assessment of their sufficiency, and there are no standards or guidance for what constitutes uniform criteria. In addition, many states are hampered by a diminished capacity to obtain the latest information technology and are discouraged from developing it because of downsizing.

Concerns with emerging infections, pandemic influenza, and the ability to respond to bioterrorism, however, are causing many state health offices to examine their communications capacities. Although the standard for laboratory reporting, for example, is still surface mail, there has been strong interest in applying computer and electronic communications technologies to laboratory reporting in states, and communications standards and systems are being developed and pilot tested in a few states. However, it is likely that even when standardized communications systems are developed there will be problems in their acquisition and maintenance because of the limited availability of well-trained information technology personnel.

Ironically, all states have been reporting their data electronically to CDC on a weekly basis for the past 10 years. However, because the communications component of intrastate surveillance systems has not improved, the timeliness of the data reported to CDC has not improved. Thus, the national reporting system has not been very effective for the timely recognition of interstate disease outbreaks.

The intrastate standard for communicating all but the most urgent messages to hospitals, providers, local health departments, and others that need to know is hard-copy mail and oral presentations. Increasingly, at the national and interstate levels, teleconferences and telephone conference calls are used to make available high-quality information on specific topics. In addition, the World Wide Web and Internet listserver groups are making timely data more readily available.

Interstate communication during outbreak detection, investigation, and control has been successful, relying on e-mail, faxes, and telephone conference calls. In addition, the CDC-based public health e-mail system, Wonder, has greatly facilitated interstate and federal-to-state communications at a time when many state governments were reluctant to spend money on e-mail and Internet access. Telephone conference calls and the expanded CDC capacity to orchestrate them have also been an invaluable part of the national public health re-

sponse capacity. For example, to coordinate and standardize state-based responses to multistate outbreaks, a group of state epidemiologists not involved in the outbreak investigation can now be readily convened to help determine the appropriate response to breaking and sometimes preliminary information from the investigations. An uninvolved group is in a better position to make decisions that are not necessarily affected by the stressful circumstances of the situation.

State agencies with Internet access are also learning how to better use the Internet, particularly as it is becoming an increasingly essential tool for communication. For example, during the 1997 Hong Kong avian influenza outbreak, government communications from Hong Kong were necessarily cautious and frequently missing essential information. Connecticut epidemiologists monitored the situation by reading the Hong Kong newspapers on the Internet and then forwarding excerpts by e-mail to neighboring state epidemiologists to help them anticipate the potential for international spread. Similarly, Rhode Island recently used its website to keep neighboring states updated regarding an acute situation involving meningococcal disease and mass vaccination.

The capacity for intrastate communication lags behind that for interstate communication. The telephone, press releases, and first class mail are still the standards for rapid communication for most states. Some states use mass fax capabilities by which they can simultaneously send one fax to a long mailing list. The Internet is still limited as a communications tool within states because many of the people who need to be reached do not have access to it. Except for universities, for example, most emergency departments, hospitals, laboratories, and physicians do not have the kind of centralized e-mail that is made possible by the CDC Wonder system.

To improve the intrastate communications capacity so that it does not handicap the rapidly developing national ability to conduct timely surveillance for and response to emerging infections, an effort is needed to formally define what minimum intrastate communications capacities and technologies are needed. It may be impossible to improve the rate of reporting, for example, without electronic reporting mechanisms and capacity. In the process of doing this, it will be possible to determine what additional resource might then be needed.

NONGOVERNMENTAL ORGANIZATIONS AND STATE PARTNERSHIPS

Kathleen Young
Executive Director, Alliance for the Prudent Use of Antibiotics

Nongovernmental organizations and partnerships play an important role in enhancing the capacity for improving the public health response to emerging infections. The Alliance for the Prudent Use of Antibiotics (APUA) (www.antibiotic.org) is the only independent organization dedicated exclusively

to curbing antibiotic resistance. APUA works in partnership with key government organizations with similar goals. Founded in 1981 out of concern for emerging antibiotic resistance, it now has 24 affiliated chapters across 90 countries. Funding comes from membership fees, private donations, government contracts, and corporate support. APUA uses research, education of practitioners, patients, and the public, surveillance, advocacy, and grassroots action to achieve its goals. Complex and urgent public health problems such as antibiotic resistance demand cooperative efforts between government and nonprofit organizations to maximize the use of resources in a timely fashion.

APUA develops its messages and programs on the basis of a number of fundamental facts: (1) antibiotic resistance is a naturally occurring phenomenon; however, human behavior can amplify or curb antibiotic resistance or the emergence and spread of resistance; (2) antibiotics are precious and exhaustible medical resources; (3) the growth rates of antibiotic resistance are higher than expected and quite alarming; (4) resistant infections are more costly to treat; (5) 50 percent of antibiotics are used in animals and agriculture; and (6) for some conditions, 50 percent of the antibiotics used in medicine are of no benefit to the patient.

APUA's global network involves a local team approach to curbing resistance. It involves microbiologists, laboratory personnel, infectious disease physicians, pharmacists, patients, and general practitioners and specialists working together in each of its chapters. APUA conducts its educational program through a website with information about antibiotic resistance (www.antibiotic.org), interviews with the media, development of patient brochures, and a lecture series that reaches approximately 7,000 physicians, residents, and nurse practitioners per year. In addition, APUA conducts advocacy activities including providing expert testimony at government hearings, preparing reports, and conducting interviews with the press.

APUA works with key government organizations involved in parallel efforts including the Centers for Disease Control and Prevention, the U.S. Agency for International Development Infections Disease Initiative, and the World Health Organization Office on Antimicrobial Resistance Monitoring. The shared objectives of these groups are to improve susceptibility tests, encourage their use, assist in national policy development, promote national surveillance, gather data on the emergence and spread of resistance, and provide information on antimicrobial resistance to governments and industry.

APUA's current work plan includes the following:

- a collaborative project with the University of Illinois, and sponsored by the National Institute of Allergy and Infectious Diseases of the National Institutes of Health, to develop a scientific collaboration and a website which will track resistance in commensal organisms (see www.ROAR.APUA.org).

- development of an integrated database of the major global surveillance systems tracking antibiotic resistance; this combined data set is intended to be used by academics to answer specific public health questions;
- a partnership with the Massachusetts Department of Public Health to test a model surveillance system that correlates antibiotic use and antibiotic resistance;
- working with the Massachusetts Society of Infectious Disease Physicians to survey all primary health care physicians concerning their prescription practices and to distribute educational information about antibiotics;
- a partnership with the Massachusetts Group Insurance Commission and Massachusetts Medicaid to explore antibiotic use in their patient populations;
- distribution of a scientific newsletter exploring the scientific and medical aspects of antibiotic resistance;
- a major national education campaign to develop and disseminate factual information concerning antibiotic use as growth promoters;
- development of small grants and training workshops to build the research capacity of APUA's 24 foreign affiliated chapters; and
- continuation of its lecture series for U.S. providers.

APUA is an example of a small nonprofit organization whose resources can be used to complement government programs and improve the quality and pace of the public health response to emerging infections.

CONTINUING EDUCATION: THE ROLE OF PROFESSIONAL ORGANIZATIONS

Scott Becker
Executive Director, Association of Public Health Laboratories

Historically, training and continuing education have been the first items cut from governmental budgets during periods of fiscal austerity. This trend is particularly troublesome in an era when the prevalence of infectious diseases is resurging and health professional education is central to their control.

Associations play a major role in education; 95 percent offer educational programs to members, and 79 percent report that they offer public information and education. In addition, associations spend $2.2 billion annually on technology. Continuing education includes workshops (in the research and clinical communities these might occur in the laboratory), conferences, symposia, distance learning, audio and video teleconferencing, and moderated Internet listserver groups. Groups that have been actively involved in communication and education activities related to emerging infectious diseases include the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), the National Governors' As-

sociation, the National Conference of State Legislators, the Council of State and Territorial Epidemiologists, and the Association of Public Health Laboratories.

The Association of Public Health Laboratories (www.aphl.org) has a training and education committee that provides oversight to the National Laboratory Network (NLTN) and is a collaborator in the Public Health Training Network (PHTN). PHTN is a model program centered at CDC and consists of a network of public, private, academic, and business organizations, including the Health Care Financing Administration, Health Resources Services Administration, FDA, Association of State and Territorial Health Officials (ASTHO), National Association of County and City Health Officials (NACCHO), nonprofit organizations, and local and state health agencies. Since 1993 PHTN has trained over 500,000 individuals.

PHTN conducts training needs assessments, enlists experts in particular subjects, and announces its programs widely. Distance learning coordinators at the city and state levels help communicate the material and coordinate activities. Supportive material is provided to the learner at the work site. PHTN courses include instruction on infections caused by resistant gram-positive organisms, antimicrobial use and resistance, good laboratory practices, and laboratory risk assessment.

The National Laboratory Training Network is jointly sponsored and administered by the Association of Public Health Laboratories and CDC. NLTN focuses on delivering training to the public health laboratory workforce. The program was initiated in 1989 in response to training needs associated with human immunodeficiency virus (HIV) and AIDS. The program has seven regional offices, all housed in state public health laboratories. The offices provide workshops and seminars and weeklong public health series courses and has a lending library. Each office has a satellite downlink so that every PHTN course is copied and available. Impact assessments are routinely conducted.

In 1997 and 1998, 268 courses were offered nationwide (2,000 students), and 126 of these were infectious disease-related. Sample courses are on molecular diagnosis of infectious diseases, viral load workshops for HIV and hepatitus C virus, and "Mad Cows and Englishmen." PHTN also has a public health series on foodborne illness and a series on virology and the influenza pandemic.

ROLE OF MEDICAL INFORMATION IN DETECTION AND MANAGEMENT OF EMERGING INFECTIONS

Edward ("Ted") Shortliffe
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The role of informatics in clinical medicine and public health is an expansive and complex topic. In that sense, emerging infections and their

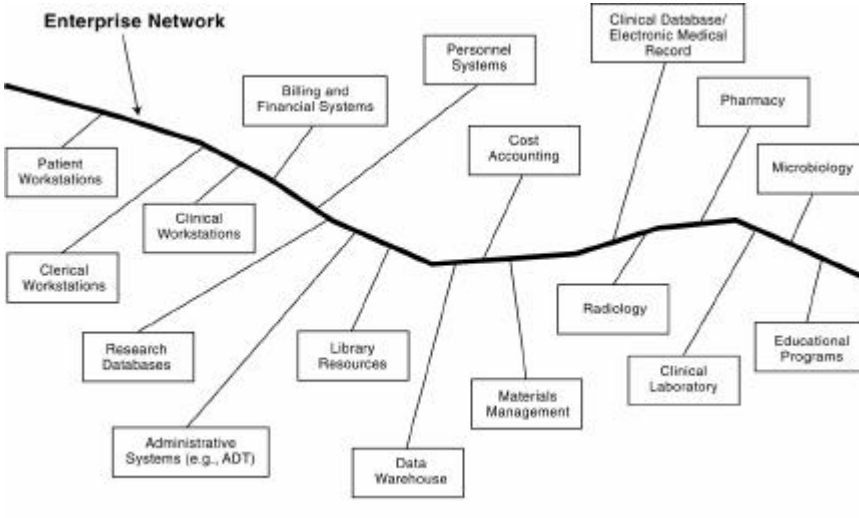

FIGURE 4-1. The Enterprise Intranet: An electronic medical record system linking clinical databases and primary and ancillary health care departments, as well as providing certain basic administrative and clerical functions. SOURCE: Edward "Ted" Shortliffe.

detection and management are not necessarily unique. Many of the issues regarding the management of emerging infections can be couched in the context of how best to deliver advice at the point of care and to develop protocols and guidelines. They are also part of a larger discussion on enterprise-wide networking and connecting laboratory and medical record systems that is occurring.

One of the most important potential applications of the Internet is the pooling and sharing of data, yet this cannot be done until there are more clearly defined standards and coordination at the regional and national levels. Clinical data must be in a form in which they can be shared across institutions.

In the health care setting, clinical workstations provide access to the pharmacy, microbiology laboratory, radiology department, the clinical laboratory, and certain basic administrative functions. Many institutions are trying to bring these components together in the form of a clinical database, which can evolve into a full electronic medical record. This type of architecture is commonly called the "enterprise intranet" (see Figure 4-1).

When clinicians use the medical record system to record data about clinical observations, the data are stored in the clinical data repository, as are all the test data that are coming from various sources, such as radiology, the clinical laboratory, and the microbiology laboratory. These data then also become useful for quality assurance, utilization review, clinical trials, or public health surveys and monitoring. Thus, to meet the goals of better data management and creation of

an infrastructure that will support emerging infection detection and management, it is important to examine how clinical data are being captured and managed within individual organizations. The privacy and confidentiality of patient data might actually be better protected with the electronic record than with the paper-based record because access can be controlled more effectively. Encryption and proper authentication technologies have advanced to the stage to ensure robust data protection if the methods are properly implemented and combined with unambiguous privacy policies and enforcement.

A significant challenge to electronic medical records comes from the methods by which information is recorded into the system by the physician. Structured data entry (rather than free-text dictation or transcription) becomes an important component in the creation of such a clinical database. This may be achieved with handheld clipboard-size machines with pen-based interfaces that have wireless connections into local networks. Data entry is through forced categories, so the captured information becomes uniform, unambiguous, and suitable for proofreading or comparison. Most importantly, these systems must be integrated with other information resource systems in the health care setting, such as clinical care and specialty service sites, and administrative and financial offices. To achieve all of this, education is paramount, as are standards development, adoption of computer-based patient records, and routine implementation of high-speed access to the Internet.

5
Strategic Planning, Resource Allocation, and Economic Support

OVERVIEW

Advocating for public health is often difficult, especially if those people and organizations that are best suited to be advocates are understaffed, have inadequate resources, and are not experienced in the art of advocacy and communication. Yet, members of the U.S. Congress, state legislators, and managed care organizations need to be educated about the needs of the public health systems, particularly the public health infrastructure. Until public health laboratories and clinical departments have the resources and infrastructures necessary to meet the challenges of emerging infectious diseases, planning may remain reactive rather than strategic.

LEGISLATION AND MANDATES AT THE FEDERAL LEVEL

Ellen Gadbois, Ph.D.
Office of Senator Edward Kennedy, United States Senate

Traditionally, the U.S. Congress has been supportive of public health activities in the area of infectious diseases, including such issues as funding of basic research and concerns about food safety and antimicrobial resistance. Moreover, members of Congress are frequently riveted by media reports of infectious diseases or foodborne outbreaks. Other issues receiving congressional attention include managed care. Other factors are at play, however, in Congress's response to emerging infectious diseases. Specific diseases are often targeted for earmarks by biomedical research advocates during the congressional appropriations process, and funding for infectious diseases is competing directly

with funding for other types of diseases as well as with other health care priorities. Infectious diseases are sometimes disadvantaged in that they are still not seen as a health threat to Americans but, instead, are seen as a problem primarily faced by people in other countries.

The larger biomedical research community approaches Congress with a clear message; that research is good for everybody and that it will make people healthier and will save Medicare dollars. This is an opportunity for the public health community to create partnerships with patient advocacy groups. Congress has come to appreciate the value of basic research and could similarly come to appreciate the need for an adequate public health infrastructure and infectious disease surveillance. The Senate Subcommittee on Public Health and Safety plans to convene hearings on issues related to infectious diseases, including bioterrorism, food safety, and antimicrobial resistance. In addition, a number of bills that will regulate food safety have been introduced.

Senator Edward Kennedy and other members are especially interested in the issue of antimicrobial resistance, which involves the activities of a number of federal agencies. For example, the National Institutes of Health's (NIH's) research portfolio includes vaccines and antibiotics, clinical diagnostics, and microbial genome sequencing, and the Centers for Disease Control and Prevention (CDC) is the lead agency for infectious disease surveillance and prevention. There are also questions about reimbursement policies at the Health Care Financing Administration (HCFA) and whether it is promoting judicious antimicrobial use. Through the U.S. Food and Drug Administration (FDA), Congress has taken several relevant actions that bear on antimicrobial resistance, including allowing fast-track development for certain drugs and exclusivity for pediatric studies of antibiotics. In addition, there has recently been considerable interest in the use of antimicrobial agents in animals. Review of agricultural issues also includes oversight and review of the activities of the U.S. Department of Agriculture. The U.S. Environmental Protection Agency plays a role with regard to regulating antibacterial household products.

In the broader context of health care, Congress is very interested in managed care reform. The patients' bill of rights proposed by Democrats allows for access to specialists, which in the case of unusual infectious diseases is important. It also allows for insurance coverage for routine patient costs associated with participation in clinical trials. These proposed policies are important considerations in terms of access to specialists in the case of exposure to unusual or rare infectious diseases. Formulary policies in the managed care systems often limit access to certain drugs, which can be detrimental in the case of someone who is infected with a drug-resistant pathogen.

The confidentiality of medical records is another topic of considerable interest to Congress and the Executive Branch, and the administration has recommended legislation on personally identifiable medical information. Most pro-

posals have special provisions for public health activities, but there is an overlap among public health, biomedical research, and health services research.

CONGRESSIONAL RESPONSE TO THE THREAT OF INFECTIOUS DISEASES

Jack Chow, Ph.D.
Senate Appropriations Committee, Labor, Health, and Human Services Subcommittee

In fiscal year 1999, the U.S. Congress gave a $3.2 billion (14.5 percent) increase to the agencies of the U.S. Public Health Service. Much of the increase was awarded to NIH, but CDC, the Agency for Health Care Policy and Research (AHCPR), and Health Resources Services Administration (HRSA) also received substantial increases. Congress and the President also funded a bioterrorism initiative, which consisted of $217 million in emergency funding, including $139 million for bioterrorism-related programs at CDC and the Office of Emergency Preparedness, as well as $28 million to be dedicated to polio and measles eradication efforts around the world.

In developing the public health budget, Congress relies on input from the agencies of the U.S. Department of Health and Human Services, hearings, and contact from a variety of interest groups. The budget for the Labor, Health and Human Services, and Education Bill presents a zero-sum situation, in which if there is increased funding for public health, that funding must come from the education and labor portions, which also have their advocates. Within the health allocations, there is always tension between the allocations for chronic diseases and those for acute diseases. Some groups, however, are more effective at advocating their causes than others. Public health, like a lot of other government endeavors, includes the intangible, but there has been a basic consensus that it is a worthwhile and rational investment. Nevertheless, federal support for public health efforts does not take into account activities at the state or private level. In addition, funding for categorical or discretionary programs often does not take into account infrastructure needs.

A legislative view of the public health infrastructure would be that it has a portfolio of material and personnel, technology information flows, and functions that produce a clear relationship between inputs and outcomes. For instance, vaccination programs have a clear value chain; creation and distribution of a product that leads to the outcome of disease suppression. This requires useful benchmarks by which to measure progress. In addition, there must be a professional cadre of public health professionals, and the training pipeline must be sustainable.

An idea that has been considered by Congress is a national health index, a singular common number that is a proxy for the state of health in a given region

and that is fungible and comparable across regions. Such an index might be helpful in guiding policy, particularly if it could be broken down into individual components by disease entity or geographic region. For instance, there might be an infectious disease index with a score that incorporates the power of prevention.

Congress is also interested in looking at emerging infectious diseases, as well as other diseases, in the context of health and international security. In the post-Cold War era, the traditional political and military model of conflict is dissolving into a rapidly changing landscape of threats and of global interdependence that could yield degradations of health and other elements of human security. Persistent poverty and chronic under- and maldevelopment in many regions of the globe contribute to population vulnerability. Instability is a prime breeding ground for emerging diseases, both infectious and noninfectious diseases, which requires that the government act not only to achieve stability but also to be prepared for bioterrorism and pandemics.

STATE HEALTH OFFICIAL PERSPECTIVE

Fred Edgar Thompson, Jr., M.D.
State Health Officer, Mississippi Department of Health

State governments have many public health responsibilities. These include conduct of surveillance, maintain the capacity to perform epidemiological investigations, and contain the expertise and experience needed to rapidly mount mass immunization campaigns. Therefore, some of these elements should not be privatized, such as the laboratory functions and epidemiology. The strategy in dealing with emerging infectious diseases and related public health problems must involve state-level public health because government will inevitably execute that strategy.

There is a range of public health activities, from investigating the background of sporadic cases of various infectious diseases, to studies of outbreaks of diseases, to the sporadic occurrence of newly emerging or reemerging infections, to bioterrorism. A fundamental infrastructure that addresses every aspect of this continuum at the local and state levels is also evident, and that infrastructure requires public resources.

A basic function of states is surveillance, primarily to receive and process reports of diagnosed cases of reportable diseases and to receive calls from local physicians and specialists about an unusual death, or reports of severe diarrhea in children, or reports of extreme respiratory distress in adults. Routine consultation is part of this fundamental process and involves a circle of human interactions. There must also be routine interaction between the public health laboratory and physicians and between epidemiologists and physicians.

States must have capacities in epidemiological investigation, which requires field staff and a response team. This requires that the state have in place the ap-

propriate personnel on an ordinary day in the event that it becomes an extraordinary day. For contact tracing and case finding, public health nurses, disease investigators, and public health environmentalists might be required.

Generally, states and large local jurisdictions have the expertise and experience needed to quickly mobilize mass immunization campaigns. Large-scale administration of medications is a function of many state health departments. It may be as simple as prophylaxis for meningococcal disease in a family or in an entire kindergarten classroom. The logistics of how to do this are skills held by state health departments, which can refine techniques based on actual experience rather than theory. Finally, state health departments are essential in disaster response.

Communication—coordination, education, and outreach—is essential to exchanging information to generate hypotheses, and it must be secure. Public health officials who are a regular, daily source of public health information for elected officials and the public are also the most effective communicators in an emergency.

With regard to resource and economic support, public health departments have inadequate resources for investigation of deaths that may be due to infectious diseases. One of the most critical needs across the country is the universal medical examiner system; however, this is not the case in every jurisdiction. Far too many fatal cases of unknown origin are under the jurisdiction of a coroner, whose only qualification might be that he or she is a registered voter in the district. Until there is regular investigation of suspicious deaths by sufficiently qualified persons, there will never be adequate surveillance for emerging infectious diseases or for a number of other potential public health problems.

In addition to sufficient financial and human resources, state health officials would also benefit from the establishment of standards of personnel qualifications and case definitions. The Council of State and Territorial Epidemiologists, the Association of Public Health Laboratories, the Association of State and Territorial Health Officials, and the National Association of City and County Health Officials must develop these standards with input from CDC and NIH.

LABORATORY-BASED REPORTING ISSUES

Robert J. Rubin, M.D.
President, The Lewin Group

Both the public and the private sectors have a role to play in effective surveillance efforts. Private-sector laboratories are more likely to detect unusual infections, report them to public health officials, and forward isolates of unusual pathogens to public-sector laboratories. It is the responsibility of public-sector laboratories to document and identify the occurrence of unusual infections. They need to know what kinds of tests to perform, such as serotyping studies, and

increasingly, they must sequence the genomes of pathogens that may threaten the public health.

Because the public health system is at a crossroads as to how to define and sustain its role, the changing face of health care poses new challenges for the detection, treatment, and prevention of infectious diseases. While historically local public health departments, hospitals, and clinics have been the main source for infectious disease outbreak detection and treatment, this trend has been changing. Now, the numbers of members of managed care organizations and the rate of privatization of public health laboratories continue to increase in response to the needs of the communities they serve. This transformation has been a controversial issue.

A study of public health laboratory directors inquired about the effects of managed care on the public health mission (Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 1997; *Public Health Infrastructure and the Private Sector: Public Health Laboratories and Managed Care;* http://aspe.hhs.gov/health/reports/phlabs/front.htm). Forty-seven percent responded negatively (i.e., managed care has no impact); 43 percent said yes (i.e., managed care has adverse impacts), 10 percent were unsure, and 2 percent did not answer. In terms of the potential positive effects, managed care plans have integrated patient databases that may be precisely what is needed to track infectious diseases that occur in that plan's population. In addition, there is a potential for seamless communication between laboratories, managed care organizations, and public health officials. Some of the negative effects include an overemphasis on economic efficiency that creates disincentives for reporting and isolate submission. In addition, comprehensive contracts with large national laboratories may create barriers to complying with state and local disease reporting requirements. There is some sense of loss of ownership and control when specimens move across state borders in an attempt to find the best price.

The public sector is behind in leveraging the potential advantages for managed care, and there are a variety of reasons for this. One of these is the fact that it is hard to obtain adequate funds for infrastructure. In addition, because many state public health laboratories consider managed care's impact to be a negative, adversarial relationships among public health officials, managed care organizations, and state legislators may develop.

Another study, funded by the American Society for Microbiology, looked at the impact of managed care and health system change on clinical laboratories (*The Impact of Managed Care and Health System Change on Clinical Microbiology*. Prepared by The Lewin Group, 1998; available at http://www.asm.org/pasrc/pdfs/lewinrep.pdf). The investigators interviewed 369 people throughout the country in a statistically valid sample of microbiologists, clinical laboratory directors, and administrators. Roughly 61 percent were from academic hospitals, 23 percent were from nonacademic hospitals, 11 percent were from independent reference laboratories, and 5 percent were from public health laboratories.

Among these respondents, managed care was perceived to be the most important market force affecting clinical laboratories. Yet, two-thirds of the respondents reported overall increases in test volumes. More respondents reported an increase than a decrease for every single type of laboratory test queried. However, 10 percent said that they had decreased the amount of antimicrobial susceptibility testing done, even though this is an era of increasing drug resistance.

About one-third of clinical directors and laboratory directors reported that they spent decreasing amounts of time actually performing tests. Two-thirds of the laboratories reported a decrease in overall staffing, and equal numbers of respondents reported an increase and a decrease in pathologists, Ph.D. microbiologists, laboratory technicians, and laboratory assistants. Between three and four times as many respondents reported a decrease than an increase in the number of mid-level positions (e.g., M.S.- or B.S.-level microbiologists or technical supervisors). More than half the laboratories surveyed had been downsized; half had developed either partnerships or affiliations with other laboratories. The vast majority of respondents reported implementing measures to control costs.

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APPENDIX A

Glossary and Acronyms

This glossary is intended to define terms commonly encountered throughout this report as well as some terms that are commonly used in the public health industry. This glossary is not all-inclusive. New terms and new usages of existing terms will emerge with time and advances in technology. Definitions for the terms presented here were compiled from a multitude of sources, which are listed at the end of the glossary.

AAFP (American Academy of Family Physicians): A national, nonprofit medical association founded to promote and maintain high-quality standards for family doctors who are providing continuing comprehensive health care to the public (www.aafp.org).

AAMC (Association of American Medical Colleges): A nonprofit association whose purpose is to improve the nation's health (www.aamc.org).

AHCPR (Agency for Health Care Policy and Research): An agency of the U.S. Department of Health and Human Services that is charged with supporting research designed to improve the quality of health care, reduce its cost, and broaden access to essential services (www.ahcpr.gov).

Academic Health Centers (AHCs): Academic health centers, or AHCs, consist of health care institutions that are owned by or closely affiliated with a university or medical school. AHCs also have at least one additional health professional program, and are engaged in undergraduate and graduate medical education, biomedical research, and delivery of patient care.

Antibiotic: Class of substances or chemicals that can kill or inhibit the growth of bacteria. Originally antibiotics were derived from natural sources (e.g., penicillin from molds), but many currently used antibiotics are semisynthetic and are modified by the addition of artificial chemical components.

Antibiotic resistance: Property of bacteria that confers the capacity to inactivate or exclude antibiotics or a mechanism that blocks the inhibitory or killing effects of antibiotics.

Antimicrobial agents: Class of substances that can destroy or inhibit the growth of pathogenic groups of microorganisms, including bacteria, viruses, parasites, and fungi.

ASM (American Society for Microbiology): The oldest and largest membership organization in the world devoted to a single life science. ASM represents 24 disciplines of microbiological specializations plus a division for microbiology educators (www.asmusa.org).

Bacteria: Microscopic, single-celled organisms that have some biochemical and structural features different from those of animal and plant cells.

Basic research: Fundamental, theoretical, or experimental investigation to advance scientific knowledge, with immediate practical application not being a direct objective.

Benchmark: For a particular indicator or performance goal, the industry measure of best performance. The benchmarking process identifies the best performance in the industry (health care or non-health care) for a particular process or outcome, determines how that performance is achieved, and applies the lessons learned to improve performance.

Broad-spectrum antibiotic: An antibiotic effective against a large number of bacterial species. It generally describes antibiotics effective against both gram-positive and gram-negative classes of bacteria.

CDC (Centers for Disease Control and Prevention): A public health agency of the U.S. Department of Health and Human Services whose mission is to promote health and quality of life by preventing and controlling disease, injury, and disability (www.cdc.gov).

Clinical practice guidelines: Systematically developed statements that assist practitioners and patients with decision making about appropriate health care for specific clinical circumstances.

Clinical research: Investigations aimed at translating basic, fundamental science into medical practice.

Clinical trials: As used in this report, research with human volunteers to establish the safety and efficacy of a drug, such as an antibiotic or a vaccine.

Clinicians: One qualified or engaged in the clinical practice of medicine, psychiatry, or psychology, as distinguished from one specializing in laboratory or research techniques in the same fields.

DHHS (U.S. Department of Health and Human Services): The U.S. government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves (www.os.dhhs.gov).

Disease: The condition in which the functioning of the body or a part of the body is interfered with or damaged. In a person with an infectious disease, the infectious agent that has entered the body causes it to function abnormally in some way or ways. The type of abnormal functioning that occurs is the disease. Usually the body will show some signs and symptoms of the problems that it is having with functioning. Disease should not be confused with infection.

Emerging infections: Any infectious disease that has come to medical attention within the last two decades or threatens to increase in the near future (IOM, 1992). Many times, such diseases exist in nature as zoonoses and emerge as human pathogens only when humans come in contact with a formerly isolated animal population, such as monkeys in a rain forest that are no longer isolated because of deforestation. Drug-resistant organisms could also be included as emerging infections since they exist because of human influence. Some recent examples of agents responsible for emerging infections include human immunodeficiency virus, Ebola virus, and multidrug-resistant *Mycobacterium tuberculosis.*

Encephalitis: An acute inflammatory disease of the brain due to direct viral invasion or to hypersensitivity initiated by a virus or other foreign protein.

Endemic: Disease that is present in a community or common among a group of people; said of a disease continually prevailing in a region.

EPED: Epidemiologist's editor as a general word processor.

EPIAIDS: A programmable word processing program within the Epidemiologist's Editor (EPED) word processor. EPIAIDS programs are provided to guide one through tutorials on the use EPED and other programs and to assist in constructing memoranda, questionnaires, and epidemiological study designs.

Etiology: Science and study of the causes of diseases and their mode of operation.

FDA (U.S. Food and Drug Administration): A public health agency of the U.S. Department of Health and Human Services charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related health laws (www.fda.gov).

FoodNet: A set of activities designed to determine and monitor the burden of foodborne diseases and improve understanding of the proportion of foodborne diseases attributable to various pathogens. It is an example of population-based surveillance in the Emerging Infections Programs.

Formulary: List of drugs approved for the treatment of various medical indications. It was originally created as a cost-control measure, but it has been

used more recently to guide the use of antibiotics on the basis of information about resistance patterns.

HMO (health maintenance organization): A health care service plan that requires its subscriber members, except in a medical emergency, to use the services of designated physicians, hospitals, or other providers of medical care. HMOs typically use a capitation payment system that rewards providers for cost-effective management of patients.

Immunogenicity: The property that endows a substance with the capacity to provoke an immune response or the degree to which a substance possesses this property.

Incidence: The frequency of new occurrences of disease within a defined time interval. Incidence rate is the number of new cases of a specified disease divided by the number of people in a population over a specified period of time, usually 1 year.

Infection: The entry and development of an infectious agent in the body of a person or animal. In an apparent, "manifest" infection, the infected person outwardly appears to be sick. In an unapparent infection, there is no outward sign that an infectious agent has entered that person at all. Infection should not be confused with disease.

Invasive isolates: A pure culture of a microorganism that is capable of (1) penetrating the host's defenses, (2) entering host cells, or (3) passing through mucosal surfaces and spreading in the body.

MCO (managed care organization): An organization that arranges for health care delivery and financing and that is designed to provide appropriate, effective, and efficient health care through organized relationships with providers. Includes formal programs for ongoing quality assurance and utilization review, financial incentives for covered members to use the plan's providers, and financial incentives for providers to contain costs. Managed care plans vary greatly in the degree to which benefit coverage is offered, monitored, and conditioned upon certain criteria being met by the subscriber member and the member's primary care physician.

Meningitis: An infection of the fluid of a person's spinal cord and the fluid that surrounds the brain. People sometimes refer to it as spinal meningitis. Meningitis is usually caused by a viral or bacterial infection.

Methicillin-resistant *Staphylococcus aureus* (MRSA): Strictly speaking, a *Staphylococcus aureus* strain resistant to the antibiotic methicillin. In practice, MRSA strains are generally resistant to many antibiotics and some are resistant to all antibiotics except vancomycin, such that the acronym is now generally used to mean "multidrug-resistant *S. aureus*."

MIC (minimum inhibitory concentration): The lowest antibiotic concentration that prevents bacterial growth.

NCID (National Center for Infectious Diseases): The division of the Centers for Disease Control and Prevention whose mission is to prevent illness, disability, and death caused by infectious diseases in the United States and around the world. NCID accomplishes its mission by conducting surveillance, epidemic investigations, epidemiological and laboratory research, training, and public education programs to develop, evaluate, and promote prevention and control strategies for infectious diseases (www.cdc.gov/ncidod/ncid.htm).

NIAID (National Institute of Allergy and Infectious Diseases): A division of the National Institutes of Health that provides the major support for scientists conducting research aimed at developing better ways to diagnose, treat, and prevent the many infectious, immunological, and allergenic diseases that afflict people worldwide (www.niaid.nih.gov).

NIH (National Institutes of Health): A public health agency of the U.S. Department of Health and Human Services whose goal is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability, from the rarest genetic disorder to the common cold (www.nih.gov).

Nosocomial infection: An infection that is acquired during hospitalization but that was neither present nor incubating at the time of hospital admission, unless it is related to a prior hospitalization, and that may become clinically manifest after discharge from the hospital.

Outpatient services: Medical and other health care services not requiring hospitalization. These services may be provided by a hospital or other qualified facility or supplier, such as mental health clinics, rural health clinics, mobile X-ray units, or freestanding dialysis units. Such services include outpatient physical therapy services, diagnostic X-ray and laboratory tests, and radiation therapy.

Primary care: Basic or general health care, traditionally provided by family practice, pediatric, and internal medicine physicians.

Program Announcement (PA): A public announcement describing the goals and scope of a proposed scientific project awaiting approval from a specific scientific organization.

Prophylactic antibiotics: Antibiotics that are administered before evidence of infection with the intention of warding off disease.

Public Health Service Act of 1944: An act to consolidate and revise the laws relating to the U.S. Public Health Service.

Sepsis: The presence of pathogenic microorganisms or their toxins in blood or other tissues.

Sentinel Surveillance Systems (SSS): A type of surveillance which relies on reports of cases of disease whose occurrence suggests that the quality of preventive or therapeutic medical care needs to be improved.

Surveillance systems: Used in this report to refer to data collection and recordkeeping to track the emergence and spread of disease-causing organisms such as antibiotic-resistant bacteria.

Vaccine: A preparation of living, attenuated, or killed bacteria or viruses, fractions thereof, or synthesized or recombinant antigens identical or similar to those found in the disease-causing organisms that is administered to raise immunity to a particular microorganism.

Zoonotic disease or infection: An infection or infectious disease that may be transmitted from vertebrate animals (e.g., a rodent) to humans.

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APPENDIX B

Workshop Agenda

Institute of Medicine
National Academy of Sciences
Advisors to the Nation on Science, Engineering, and Medicine

FORUM ON EMERGING INFECTIONS

Public Health Systems: Assessing Capacities to Respond to Emerging Infections

November 2–3, 1998

MONDAY, NOVEMBER 2, 1998

8:30 a.m. **Welcome and Opening Remarks**
Joshua Lederberg, Ph.D.
Chair, Forum on Emerging Infections
Sackler Foundation Scholar, The Rockefeller University

8:45 **Keynote Address**
The Changing Landscape of Public Health Systems
Peggy Hamburg, M.D., Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services

9:30–1:00 **EPIDEMIOLOGICAL INVESTIGATION**
Moderator: James Hughes, M.D.
Assistant Surgeon General, and Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention

9:30 **National Perspective for Outbreak Investigation**
Steve Ostroff, M.D., Associate Director for Epidemiologic Science, National Center for Infectious Diseases, Centers for Disease Control and Prevention

9:50 **State Perspective for Outbreak Investigation**
Patricia Quinlisk, M.D., Iowa Department of Health, and President, Council of State and Territorial Epidemiologists

10:10 **County-Level Perspective for Outbreak Investigation**
Catherine Slemp, M.D., M.P.H., Director, Infectious Disease Epidemiology Programs, West Virginia Department of Health

10:30 **The Physician Community**
Larry Strausbaugh, M.D., Epidemiologist, VA Medical Center, Portland, Oregon

10:50 **Public Health Practice and the Role of Academic Public Health**
William L. Roper, M.D., M.P.H., Dean, School of Public Health, University of North Carolina at Chapel Hill

11:10 **Break**

11:20 **PANEL DISCUSSION**
Panel Members
Speakers:
- Steve Ostroff, M.D.
- Patricia Quinlisk, M.D.
- Catherine Slemp, M.D., M.P.H.
- Larry Strausbaugh, M.D.
- William L. Roper, M.D., M.P.H.

Invited Panelists:
- Ellen Morrison, M.D., Division of Emergency Operations, Office of Regulatory Affairs, Food and Drug Administration
- Gianfranco Pezzino, M.D., State Epidemiologist, Kansas
- Department of Health and Environment

1:00 p.m. **Lunch**

2:00–5:30 **SURVEILLANCE**
Moderator: Michael Osterholm, Ph.D., M.P.H.
State Epidemiologist and Chief, Acute Disease Epidemiology Section, Minnesota Department of Health

2:00 **GAO Report on Public Health Surveillance of Emerging Infectious Diseases**
Marsha Lillie-Blanton, Ph.D., Associate Director, Health, Education, and Human Services Division, General Accounting Office
Helene Toiv, M.P.A., Assistant Director, Health, Education, and Human Services Division, General Accounting Office

2:20 **Emerging Infections Program Cooperative Agreement**
Robert Pinner, M.D., Special Assistant for Surveillance, National Center for Infectious Diseases, Centers for Disease Control and Prevention

2:40 **Large National Commercial Laboratory**
Linda Miller, Ph.D., Assistant Director, Clinical Microbiology, SmithKline Beecham Pharmaceuticals R&D

3:00 **Public-Sector Laboratory at the National Level**
Joe McDade, Ph.D., Acting Deputy Director, National Center for Infectious Diseases, Centers for Disease Control and Prevention

3:20 **The Emerging Role of the Public Health Laboratory in Meeting the Challenge of Emerging Infectious Diseases**
Mary Gilchrist, Ph.D., Director, University of Iowa Hygienic Laboratory

3:40 **Break**

3:50 **PANEL DISCUSSION**
Panel Members
Speakers:
- Marsha Lillie-Blanton, Ph.D.
- Helene Toiv, M.P.A.
- Robert Pinner, M.D.
- Linda Miller, Ph.D.
- Joe McDade, Ph.D.
- Mary Gilchrist, Ph.D.

Invited Panelists:
- Eileen Koski, M.Phil, Manager, Medical Data Applications, Quest Diagnostics
- Laurence McCarthy, Ph.D., Chief Executive Officer, MRL Pharmaceuticals, Inc.

- Eric Blank, Dr.P.H. Director, State Public Health Laboratory, Missouri; and President, Association of Public Health Laboratories

5:30 **Adjourn**

TUESDAY, NOVEMBER 3, 1998

8:30 a.m. **Opening Remarks**
Joshua Lederberg, Ph.D.
Chair, Forum on Emerging Infections
Sackler Foundation Scholar, The Rockefeller University

8:40–12:00 **COMMUNICATION AND COORDINATION, EDUCATION AND OUTREACH**
Moderator: Renu Gupta, M.D.
Vice President, Medical Safety and Therapeutics, Covance Inc.

8:40 **Communication and Coordination at the National Level: The PULSENET Model**
Bala Swaminathan, Ph.D., Chief, Foodborne Diarrheal Diseases Laboratory Section, National Center for Infectious Diseases, Centers for Disease Control and Prevention

9:00 **Communication and Coordination at the State Level**
James Hadler, M.D., M.P.H., Director, Infectious Diseases Division, Connecticut Department of Health

9:20 **Nongovernment Organizations and Partnerships**
Kathleen Young, Executive Director, Alliance for the Prudent Use of Antibiotics

9:40 **Continuing Education: The Role of Professional Organizations**
Scott Becker, Executive Director, Association of Public Health Laboratories

10:00 **The Role of Medical Informatics in the Detection and Management of Emerging Infections**
Ted Shortliffe, M.D., Associate Dean, Information Resources and Technology, Stanford University

10:20 **Break**

10:30 **PANEL DISCUSSION**
Panel Members
Speakers:
- Bala Swaminathan, Ph.D.
- James Hadler, M.D., M.P.D.
- Kathleen Young
- Scott Becker
- Ted Shortliffe, M.D.

Invited Panelists:
- Cheryl Beversdorf, Association of State and Territorial Health Officials
- JoAnne Glisson, Vice President, American Clinical Laboratory Association
- Patricia Quinlisk, M.D., Iowa Department of Health; and President, Council of State and Territorial Epidemiologists

12:00 noon **Lunch**

1:20–4:30 **STRATEGIC PLANNING, RESOURCE ALLOCATION AND ECONOMIC SUPPORT**
Moderator: Gail Cassell, Ph.D.
Vice President for Infectious Diseases Research, Drug Discovery Research, and Clinical Investigation, Eli Lilly & Company

1:20 **Legislation and Mandates at the Federal Level**
Ellen Gadbois, Ph.D., Office of Senator Edward Kennedy

1:40 **The Congressional Response to the Threat of Infectious Diseases**
Jack Chow, Ph.D., Senate Appropriations Committee, Labor, Health, and Human Services Subcommittee

2:00 **State Health Official Perspective**
Fred Edgar Thompson, Jr., M.D. State Health Officer, Mississippi Department of Health; and President, Association of State and Territorial Health Officers

2:20 **Laboratory-Based Reporting Issues**
Robert Rubin, M.D., President and Chief Operating Officer, The Lewin Group

2:40 **Break**

2:50 **PANEL DISCUSSION**
Panel Members
Speakers:
- Ellen Gadbois, Ph.D.
- Jack Chow, Ph.D.
- Fred Edgar Thompson, M.D.
- Robert Rubin, M.D.

Invited Panelists:
- Tracey Hooker, Director, Prevention Projects, National Conference of State Legislators
- James Pearson, M.D., DGS Deputy Director, Division of Consolidated Laboratory Services, Commonwealth of Virginia
- Judy Buckalew, Office of Senator Lauch Faircloth
- Donna Crane, Director of Congressional Affairs, American Public Health Association

4:30–5:30 **Summary and Concluding Remarks**
Moderator: Joshua Lederberg, Ph.D.

4:30 **Summary and Discussion with Session Moderators**

5:20 **Closing Remarks**
Joshua Lederberg, Ph.D.

5:30 **Adjourn**

APPENDIX C
Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance

SUMMARY

Pursuant to a congressional request, GAO reviewed the nation's infectious diseases surveillance network, focusing on the: (1) extent to which states conduct public health surveillance and laboratory testing of selected emerging infectious diseases; (2) problems state public health officials face in gathering and using laboratory-related data in the surveillance of emerging infectious diseases; and (3) assistance that the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) provides to states for laboratory-related surveillance and the value of this assistance to state officials.

GAO noted that: (1) surveillance and testing for important emerging infectious diseases are not comprehensive in all states, leaving gaps in the nation's infectious diseases surveillance network; (2) GAO's survey found that most states conduct surveillance of five of the six emerging infectious diseases GAO asked about, and state public health laboratories conduct tests to support state surveillance of four of the six; (3) over half of the state laboratories do not conduct tests for surveillance of hepatitis C and penicillin-resistant S. pneumoniae; (4) many state epidemiologists believe that their infectious diseases surveillance programs should expand, and they cited a need to gather more information on antibiotic-resistant diseases; (5) just over half of the state public health laborato-

This Appendix reprints material extracted from the U.S. General Accounting Office Report, *Emerging Infectious Diseases: Consensus on Needed Laboratory Capacity Could Strengthen Surveillance*, Report to the Chairman, Subcommittee on Public Health, Committee on Health, Education, Labor, and Pensions, U.S. Senate (February 1999, Rep. No. GAO/HEHS-99-26).

ries have access to advanced molecular technology, which could be valuable to all states' diseases surveillance efforts; (6) few states require the routine submission of specimens or isolated quantities of a pathogen from patients with certain diseases for testing in state laboratories—a step CDC has urged them to adopt to improve the quality of surveillance information; (7) many state laboratory directors and epidemiologists reported that inadequate staffing and information-sharing problems hinder their ability to generate and use laboratory data to conduct infectious diseases surveillance; (8) participants in the surveillance network often lack basic computer hardware or integrated systems to allow them to rapidly share information; (9) many state officials told GAO that they did not have sufficient staffing and technology resources, and public health officials have not agreed on a consensus definition of the minimum capabilities that state and local health departments need to conduct infectious diseases surveillance; (10) this lack of consensus makes it difficult to assess resource needs; (11) most state laboratory directors and epidemiologists placed high value on CDC's testing and consulting services, training, and grant funding and said these services were critical to their ability to use laboratory data to detect and monitor emerging infections; (12) state officials said CDC needs to better integrate its data systems and help states build systems that link them to local and private surveillance partners; and (13) state officials would like CDC to provide more hands-on training experience.

Continued on next page

LETTER

United States General Accounting Office
Health, Education, and Human Services Division
Washington, DC 20548

B-280933

February 5, 1999

The Honorable Bill Frist
Chairman, Subcommittee on Public Health
Committee on Health, Education, Labor, and Pensions
United States Senate

Dear Mr. Chairman:

The spread of infectious diseases is a public health problem once thought to be largely under control. However, outbreaks over the last decade illustrate that infectious diseases remain a serious public health threat. For example, in 1993, more than 400,000 people became ill from a city's drinking water contaminated with *Cryptosporidium parvum*—a common parasite resistant to chlorination and other water treatment measures. Over 4,000 people were hospitalized, and 55 died. In 1996, drinking apple juice contaminated with a virulent strain of *E. coli* bacteria made more than 60 people seriously ill and caused the death of one person. And in 1998, 26 children became ill from playing in a swimming pool contaminated by a virulent strain of *E. coli*. Four of the children developed a serious complication that affects the blood and kidneys.

The resurgence of some infectious diseases is particularly alarming because previously effective forms of control are breaking down. For example, some pathogens (disease-causing organisms) have become resistant to antibiotics used to bring them under control or have developed strains that no longer respond to the antibiotics.

Monitoring infectious diseases—identifying diseases and their sources—is critical for determining control and prevention efforts. Public health officials refer to this activity as surveillance—the ongoing collection, analysis, and interpretation of disease-related data to plan, implement, and evaluate public health actions. Many public health experts have raised concerns about the adequacy of the nation's infectious diseases surveillance network, especially for those diseases considered to be emerging—that is, ones more prevalent now than 20 years ago or ones that show signs of becoming more prevalent in the near future.

In light of these concerns, you asked us to examine the nation's surveillance network and to focus on the contribution of laboratories, since new technology

gives them an increasingly important role in identifying pathogens and the sources of outbreaks. Specifically, you asked us to (1) determine the extent to which states conduct public health surveillance and laboratory testing of selected emerging infectious diseases, (2) identify the problems state public health officials face in gathering and using laboratory-related data in the surveillance of emerging infectious diseases, and (3) describe the assistance that the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) provides to states for laboratory-related surveillance and the value of this assistance to state officials.

To provide information on the contribution of laboratories to the surveillance network, we surveyed the directors of all state public health laboratories and infectious diseases epidemiology[1] programs that report disease-related information directly to CDC, including officials in all 50 states, 5 territories, the District of Columbia, and New York City.[2] We also conducted case studies in Kentucky, New York, and Oregon; spoke with additional state and local public health officials around the country; and interviewed CDC officials. We focused our work on six specific emerging infectious diseases or pathogens: tuberculosis, Shiga-like toxin-producing *E. coli* (including *E. coli* O157:H7)[3] pertussis, *Cryptosporidium parvum*, hepatitis C virus, and penicillin-resistant *Streptococcus pneumoniae*. Our methodology is described in more detail in appendix I, the results from our surveys are in appendixes II and III, and details on the six diseases are in appendix IV. Our work was conducted from December 1997 through December 1998 in accordance with generally accepted government auditing standards.

Results in Brief

Surveillance and testing for important emerging infectious diseases are not comprehensive in all states, leaving gaps in the nation's infectious diseases surveillance network. Our survey found that most states conduct surveillance of five of the six emerging infectious diseases we asked about, and state public health laboratories conduct tests to support state surveillance of four of the six. However, over half of the state laboratories do not conduct tests for surveillance of hepatitis C and penicillin-resistant *S. pneumoniae*. Many state epidemiologists believe that their infectious diseases surveillance programs should expand, and they frequently cited a need to gather more information on antibiotic-resistant diseases. Just over half of the state public health laboratories have ac-

[1]Epidemiology is the study of the distribution and causes of disease or injury in a population.

[2]Throughout this report, we refer to this group collectively as "states."

[3]Shiga-like toxin-producing *E. coli* belong to a group of virulent *E. coli* that can produce severe intestinal bleeding. Throughout this report, we will refer to the group by the name of its most well-known member, *E. coli* 0157:H7.

cess to advanced molecular technology, which many experts believe could be valuable to all states' diseases surveillance efforts. Furthermore, few states require the routine submission of specimens or isolated quantities of a pathogen from patients with certain diseases for testing in state laboratories—a step CDC has urged them to adopt to improve the quality of surveillance information.

Many state laboratory directors and epidemiologists reported that inadequate staffing and information-sharing problems hinder their ability to generate and use laboratory data to conduct infectious diseases surveillance. For example, they believe that the number of laboratory staff to perform tests and the number of epidemiology staff who can analyze data and translate surveillance information into disease prevention and control activities are insufficient. They also cited a need for training to ensure that their staffs have the skills to take advantage of technological advances in laboratory methods, information-sharing systems, or both. Participants in the surveillance network, particularly at the local level, often lack basic computer hardware or integrated systems to allow them to rapidly share information. State officials also expressed concerns about CDC's many separate data reporting systems, which result in duplication of effort and drain scarce staff resources. Although many state officials told us that they did not have sufficient staffing and technology resources, public health officials have not agreed on a consensus definition of the minimum capabilities that state and local health departments need to conduct infectious diseases surveillance. This lack of consensus makes it difficult to assess resource needs. We are recommending that the Director of CDC lead an effort to help federal, state, and local public health officials create consensus on the core capacities needed at each level of government.

CDC provides state and local health departments with a wide range of technical, financial, and staff resources to help maintain or improve their ability to detect and respond to emerging infectious disease threats. Most state laboratory directors and epidemiologists placed high value on CDC's testing and consulting services, training, and grant funding and said these services were critical to their ability to use laboratory data to detect and monitor emerging infections. However, they identified a number of ways in which these services could be improved. Specifically, most state officials said CDC needs to better integrate its data systems and help states build systems that link them with local and private surveillance partners. Many state officials would also like CDC to provide more hands-on training experience. State officials also pointed out that obtaining assistance with problems that cut across programmatic boundaries could be improved if CDC's departments that focus on specific diseases communicated better with one another.

Conclusions

Public health officials agree that the importance of infectious diseases surveillance cannot be overemphasized. The nation's surveillance network is considered the first line of defense in detecting and identifying emerging infectious diseases and providing essential information for developing and assessing prevention and control efforts. Laboratories play an increasingly vital role in infectious diseases surveillance, as advances in technology continually enhance the specificity of laboratory data and give public health officials new techniques for monitoring emerging infections.

Public health officials who spoke with us said that the nation's surveillance system is essentially sound but in need of improvement. They point to outbreaks rapidly identified and contained as visible indications of the system's strength. Our survey results tend to support this view: surveillance of five of the six emerging infectious diseases we asked about is widespread among states, and surveillance of four of the six is supported by testing in state public health laboratories. Officials also view CDC's support as essential and are generally very satisfied with both the types and levels of assistance CDC provides.

However, our survey also revealed gaps in the infectious diseases surveillance network. Just over half of the state public health laboratories have access to molecular technology that many experts believe all states could use, and few states require the routine submission of specimens to their state laboratories for testing—a step urged by CDC. In addition, many state epidemiologists believe their surveillance programs do not sufficiently study all infectious diseases they consider important, including antibiotic-resistant conditions and hepatitis C.

Both laboratory directors and epidemiologists expressed concerns about the staffing and technology resources they have for surveillance and information sharing. They were particularly frustrated by the lack of integrated information systems within CDC and the lack of integrated systems linking them with other public and private surveillance partners. CDC's continued commitment to integrating its own data systems and to helping states and localities build integrated electronic data and communication systems could give state and local public health agencies vital assistance in carrying out their infectious diseases surveillance and reporting responsibilities.

The lack of a consensus definition of what constitutes an adequate infectious diseases surveillance system may contribute to some of the shortcomings in the surveillance network. For example, state public health officials assert that they lack sufficient trained epidemiologic and laboratory staff to adequately study infectious diseases, as well as sufficient resources to take full advantage of advances in laboratory and information-sharing technology. Without agreement on the basic surveillance capabilities state and local health departments should have, however, it is difficult for policymakers to assess the adequacy of existing resources or to identify what new resources are needed to carry out state and

local surveillance responsibilities. Moreover, public health officials make decisions about how to spend federal dollars to enhance state surveillance activities without such criteria to evaluate where investments are needed most.

Recommendation to the Director of CDC

To improve the nation's public health surveillance of infectious diseases and help ensure adequate public protection, we recommend that the Director of CDC lead an effort to help federal, state, and local public health officials create consensus on the core capacities needed at each level of government. The consensus should address such matters as the number and qualifications of laboratory and epidemiologic staff, laboratory and information technology, and CDC's support of the nation's infectious diseases surveillance system.

Agency Comments

CDC officials reviewed a draft of this report. They generally concurred with our findings and recommendation and provided technical or clarifying comments, which we incorporated as appropriate. Specifically, CDC agreed that a clearer definition of the needed core epidemiologic and laboratory capacities at the federal, state, and local levels would be useful and that integrated surveillance systems are important to comprehensive prevention programs. CDC noted that it is working with other HHS agencies to address these critical areas.

We also provided the draft report to APHL and CSTE. APHL officials said the report was comprehensive and articulated the gaps in the current diseases surveillance system well. They also provided technical comments, which we incorporated as appropriate. CSTE officials did not provide comments.

As agreed with your office, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of HHS, the Director of CDC, the directors of the state epidemiology programs and public health laboratories included in our survey, and other interested parties. We will make copies available to others upon request.

If you or your staff have any questions, please contact me or Helene Toiv, Assistant Director, at (202) 512-7119. Other major contributors are included in appendix V.

Sincerely yours,

Bernice Steinhardt
Director Health Services Quality and Public Health Issues

APPENDIX D

Forum Member and Staff Biographies

FORUM MEMBERS

JOSHUA LEDERBERG, Ph.D., is Professor emeritus of Molecular Genetics and Informatics and Sackler Foundation Scholar at The Rockefeller University, New York, N.Y. His lifelong research, for which he received the Nobel Prize in 1958, has been in genetic structure and function in microorganisms. He has a keen interest in international health and was co-chair of a previous Institute of Medicine Committee on Emerging Microbial Threats to Health (1990–1992). He has been a member of the National Academy of Sciences since 1957 and is a charter member of the Institute of Medicine. Dr. Lederberg is the chair of the Forum on Emerging Infections.

VINCENT AHONKHAI, M.D., is Vice President and Director at SmithKline Beecham Pharmaceuticals and is responsible for Clinical R&D and Medical Affairs in Anti-Infectives and Biologicals, North America. He has held this position since 1995, overseeing a product portfolio that includes antibiotics, antivirals, and vaccines. After completing medical school and internships in Nigeria, Dr. Ahonkhai obtained additional training in pediatric residency, followed by a fellowship in infectious diseases in adults and pediatrics at the State University of New York–Downstate Medical Center, Brooklyn, N.Y., from 1975 to 1980. He then joined the faculty as Assistant Professor, Department of Pediatrics. In 1982, Dr. Ahonkhai started his pharmaceutical industry career as Associate Director, Infectious Diseases, at Merck, where he rose to director level. Subsequently, he moved to the Robert Wood Johnson Pharmaceutical Research Institute, where he served first as Head of Infectious Diseases and later as Executive

Director, Dermatology and Wound Healing. Dr. Ahonkhai is board-certified in pediatrics and is a long-standing member and fellow of several professional organizations including the American Medical Association, National Medical Association, American Society for Microbiology, Infectious Diseases Society of America (fellow), Pediatric Infectious Diseases Society, and American Academy of Pharmaceutical Physicians (Vice President, Membership Development Committee, and board member).

STEVEN J. BRICKNER, Ph.D., is Manager of Medicinal Chemistry at Pfizer Central Research, where he leads a team of medicinal chemists that is focused on the discovery and development of new antibacterial agents designed to meet the growing problems with resistance. He has more than 15 years of pharmaceutical industrial research experience, all directed at the discovery of novel antibiotics. Before joining Pfizer, he led a team that discovered and developed linezolid, the first oxazolidinone to undergo phase III clinical evaluation. Dr. Brickner is recognized as a world expert on this new class of antibacterial agents.

GAIL H. CASSELL, Ph.D., is Vice President, Infectious Diseases Research, Drug Discovery Research, and Clinical Investigation at Eli Lilly & Company. Previously, she was the Charles H. McCauley Professor and (since 1987) Chair, Department of Microbiology, University of Alabama Schools of Medicine and Dentistry at Birmingham, a department which ranked first in research funding from the National Institutes of Health since 1989 under her leadership. She is a member of the Director's Advisory Committee of the national Centers for Disease Control and Prevention. Dr. Cassell is past president of the American Society for Microbiology, a former member of the National Institutes of Health Director's Advisory Committee, and a former member of the Advisory Council of the National Institute of Allergy and Infectious Diseases. She also has served as an adviser on infectious diseases and indirect costs of research to the White House Office on Science and Technology and was previously chair of the Board of Scientific Councilors of the National Center for Infectious Diseases Centers for the Centers for Disease Control and Prevention. Dr. Cassell served 8 years on the Bacteriology-Mycology-II Study Section and served as its chair for 3 years. She serves on the editorial boards of several prestigious scientific journals and has authored over 250 articles and book chapters. She has been intimately involved in the establishment of science policy and legislation related to biomedical research and public health. Dr. Cassell has received several national and international awards and an honorary degree for her research on infectious diseases.

GARY CHRISTOPHERSON, is Senior Advisor for Force Health Protection at the U.S. Department of Defense, Reserve Affairs. Previously, as Principal Deputy Assistant Secretary of Defense for Health Affairs, he managed policy, the

Defense Health Program budget and performance for the Military Health System, including the $16 billion TRICARE health care system and force health protection. In that role, he also launched the Department of State's infectious disease surveillance and response system and served as co-chair on the White House's infectious disease surveillance and response subcommittee. He has also been a key figure in the Department's force health protection initiative against anthrax. In early 1998, he also served as the Acting Assistant Secretary of Defense for Health Affairs. Joining the Department of Defense in 1994, he has served as Health Affairs' Acting Principal Deputy Assistant Secretary and Senior Advisor where he provided advice on a wide range of health issues and managed the relationships with the White House and other federal agencies. Previously, he served 2 years (1992-1994) with the Office of Presidential Personnel at the White House and the Presidential Transition Office. As Associate Director, he managed the President's appointments (PAS/PA/SES level) to the Departments of Health and Human Services and Defense as well as 10 other Departments. Prior to that, he served in a number of senior health positions with the Congress and with public and private public health agencies.

GORDON DeFRIESE, Ph.D., is Professor of Social Medicine, Epidemiology, and Health Policy and Administration and Director of the Cecil G. Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill. He received his Ph.D. from the University of Kentucky College of Medicine. Some of his research interests are in the areas of health promotion and disease prevention, medical sociology, primary health care, rural health care, cost-benefit analysis, and cost-effectiveness. He is a member of the Global Advisory Group on Health Systems Research of the World Health Organization in Geneva, past president of the Association for Health Services Research and the Foundation for Health Services Research, and a fellow of the New York Academy of Medicine. He is founder of the Partnership for Prevention, a coalition of private-sector business and industry organizations, voluntary health organizations, and state and federal public health agencies based in Washington, D.C., that have joined together to work toward the elevation of disease prevention among the nation's health policy priorities.

CEDRIC E. DUMONT, M.D., is Medical Director for the Office of Medical Services (MED) at the U.S. Department of State. Dr. Dumont graduated from Columbia University with a B.A. in 1975 and obtained his medical degree from Tufts University School of Medicine in 1980. Dr. Dumont is a board-certified internist with subspecialty training in infectious diseases. He completed his internal medicine residency in 1983 and infectious diseases fellowship in 1988 at Georgetown University Hospital in Washington, D.C. Dr. Dumont has been a medical practitioner for over 19 years, 2 of which included service in the Peace Corps. Since joining the Department of State in 1990, he has had substantial

experience overseas in Dakar, Bamako, Kinshasa and Brazzaville. For the past 3 years, as the Medical Director for the Department of State, Dr. Dumont has promoted the health of all United States Government employees serving overseas by encouraging their participation in a comprehensive health maintenance program and by facilitating their access to high-quality medical care. Dr. Dumont is a very strong supporter of the professionalal development and advancement of MED's highly qualified profession staff. In addition, he has supported and encouraged the use of an electronic medical record, which will be able to monitor the health of all its beneficiaries, not only during a specific assignment but also throughout their career in the Foreign Service.

NANCY CARTER-FOSTER, M.S.T.M., is Director of the U.S. Department of State's Emerging Infectious Diseases Program and is responsible for heading the department's policy coordination on infectious diseases and human immunodeficiency virus-AIDS issues and integrating international health issues with economic and national security implications into U.S. foreign policy. She coordinates with Unted States embassies, missions, and agencies to address global infectious disease priorities and to effect a unified United States' government response. Ms. Carter-Foster has been a foreign affairs advisor to the former Majority Whip of the U.S. House of Representatives, Congressman William H. Gray, and was the U.S. Chief Negotiator on international population issues, and the roles and status of women and international health issues which led to the United Nation's (UN) World Conference on Population and Development, the UN Conference on Environment and Development (UNCED), and in a myriad of other bilateral and multilateral fora. She also has a background in environmental systems management, ocean affairs, law of the sea, and coastal zone development.

JESSE GOODMAN, M.D., **M.P.H.,** was Professor of Medicine and Chief of Infectious Diseases at the University of Minnesota, and is now serving as Deputy Medical Director for the U.S. Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research, where he is active in a broad range of policy issues. After joining the FDA Commissioner's Office, he has worked closely with several centers and helped coordinate FDA's response to the antimicrobial resistance problem. He is also co-chair of a recently formed federal interagency task force to develop a national action plan on antimicrobial resistance. He graduated from Harvard College and attended the Albert Einstein College of Medicine followed by internal medicine, hematology, oncology, and infectious diseases training at the University of Pennsylvania and University of California Los Angeles, where he was also Chief Medical Resident. He received his master's of public health from the University of Minnesota. In recent years, his laboratory's research has focused on the molecular pathogenesis of tickborne diseases. His laboratory isolated the etiological intracellular agent of the emerging tickborne infection, human granulocytic ehrlichiosis, and has recently

identified its leukocyte receptor. He has also been an active clinician and teacher and has directed or participated in major multi-center clinical studies. He has been active in community public health activities, including an environmental health partnership in St. Paul, Minnesota. Among several honors, he has been elected to the American Society for Clinical Investigation.

RENU GUPTA, M.D., is Vice President, Medical, Safety and Therapeutics of Covance. As an infectious disease specialist, Dr. Gupta is active in a number of professional societies, including the Infectious Diseases Society of America and the American Society for Microbiology, where she is a member of the committee on education. She is a frequent presenter at the Interscience Conference on Antimicrobial Agents and Chemotherapy and other major infectious disease congresses, and has been published in leading infectious disease periodicals such as the *Journal of Virology*, the *Journal of Infectious Diseases*, and *Antimicrobial Agents and Chemotherapy*. Dr. Gupta received her M.B., Ch.B. from the University of Zambia. Subsequently, she served as Chief Resident in Pediatrics at the Albert Einstein Medical Center and as a Fellow in Infectious Diseases at the Children's Hospital of Philadelphia. She was also Postdoctoral Fellow in Microbiology at the University of Pennsylvania and the Wistar Institute of Anatomy and Biology, where she conducted research on the pathogenesis of infectious diseases. From 1989 to mid-1998, Dr. Gupta was with Bristol-Myers Squibb Company, where she directed clinical research as well as strategic planning for the Infectious Diseases and Immunology Division. For the past several years, her work has focused on a better understanding of the problem of emerging infections. Dr. Gupta currently chairs the steering committee for the SENTRY Antimicrobial Surveillance Program.

MARGARET A. HAMBURG, M.D., is the Assistant Secretary for Planning and Evaluation of the U.S. Department of Health and Human Services. Previously she was the Health Commissioner for the City of New York. She holds appointments as Adjunct Assistant Professor of Medicine at the Cornell University Medical Center and Assistant Professor of Public Health at the Columbia University School of Public Health. In her previous position as special assistant to National Institute of Allergy and Infectious Diseases Director Anthony Fauci, M.D., she played a major role in research administration and policy development in the area of infectious diseases. She serves on the Board of Scientific Counselors of the Center for Infectious Diseases at the Centers for Disease Control and Prevention. She received her M.D. from Harvard Medical School and completed her internship and residency in internal medicine at New York Hospital/Cornell Medical Center and is board-certified in internal medicine. Dr. Hamburg is the author of many scientific articles and is the recipient of numerous awards for distinguished public service.

CAROLE A. HEILMAN, Ph.D., is Director of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID). Dr. Heilman received her bachelor's degree in biology from Boston University in 1972, and earned her master's degree and doctorate in microbiology from Rutgers University in 1976 and 1979. Dr. Heilman began her career at the National Institutes of Health as a postdoctoral research associate with the National Cancer Institute where she carried out research on the regulation of gene expression during cancer development. In 1986, she came to NIAID as the influenza and viral respiratory diseases program officer in DMID and, in 1988, she was appointed chief of the respiratory diseases branch where she coordinated the development of acellular pertussis vaccines. She joined the Division of AIDS as deputy director in 1997 and was responsible for developing the Innovation Grant Program for Approaches in human immunodeficiency virus vaccine research. She is the recipient of several notable awards for outstanding achievement. Throughout her extramural career, Dr. Heilman has contributed articles on vaccine design and development to many scientific journals and has served as a consultant to the World Bank and the World Health Organization in this area. She is also a member of several professional societies, including the Infectious Diseases Society of America, the American Society for Microbiology, and the American Society of Virology.

DIETER HINZEN, Ph.D., Biographical data not available.

JAMES M. HUGHES, M.D., is Assistant Surgeon General and Director of the National Center for Infectious Diseases (NCID) at the Centers for Disease Control and Prevention (CDC). He was named Deputy Director of NCID in 1988 and became Director of the Center in 1992. He joined CDC as an Epidemic Intelligence Service Officer in 1973, during which time he focused on the epidemiology of foodborne, waterborne, and other diarrheal diseases. Dr. Hughes received his M.D. in 1971 from Stanford University. He is board-certified in internal medicine, infectious diseases, and preventive medicine. He is a Fellow of the American College of Physicians and the Infectious Diseases Society of America.

J. STANLEY HULL is Vice President of Marketing for Gastrointestinal and Anti-Infectives Research at Glaxo Wellcome. He is responsible for developing revenue forecasts and expense budgets and for reviewing marketing plans for these therapeutic areas. More of his attention is given to pipeline products to ensure that these products are developed to meet customer needs. Before taking his current position, he served as Vice President of Marketing for Glaxo Pharmaceuticals, where he was involved in the commercial development of products in the gastrointestinal, antibacterial, anesthesia, and antiviral therapeutic areas. He has served in various sales and marketing positions in the pharmaceutical industry

since he began his career in 1978. He holds a B.S. degree in business administration and economics from the University of North Carolina at Greensboro.

SAMUEL L. KATZ, M.D., is Chairman of the Board of the Burroughs Wellcome Fund and Wilburt C. Davison Professor and Chairman emeritus of pediatrics at Duke University Medical Center. He has concentrated his research on infectious diseases, focusing primarily on vaccine research and development, having developed the attenuated measles virus vaccine with Nobel Laureate John F. Enders. He is a past chair and a member of the Public Policy Council of the Infectious Diseases Society of America. Dr. Katz has served on a number of scientific advisory committees and is the recipient of many prestigious awards and honorary fellowships in international organizations. Dr. Katz attained his M.D. from Harvard Medical School. After his medical internship at Beth Israel Hospital, he completed his pediatrics residency training at the Massachusetts General Hospital and the Boston Children's Hospital. Then he became a staff member at Children's Hospital, working with Nobel Laureate John F. Enders, during which time they developed the attenuated measles virus vaccine now used throughout the world. He has chaired the Committee on Infectious Diseases of the American Academy of Pediatrics (the Redbook Committee), the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, the Vaccine Priorities Study of the Institute of Medicine (IOM), and several World Health Organization (WHO) and Children's Vaccine Initiative panels on vaccines and human immunodeficiency virus infections. He is a member of many scientific advisory committees and boards including those of the National Institutes of Health, IOM, and WHO. Dr. Katz's published studies include more than 100 original scientific articles, 60 chapters in textbooks, and many abstracts, editorials, and reviews. He is the coeditor of a textbook on pediatric infectious diseases and has given more than 70 named lectures in the United States and abroad.

KENNETH W. KIZER, M.D., M.P.H., is President and Chief Executive Officer of the National Quality Forum. Formerly, he served as the Under Secretary for Health at the U.S. Department of Veterans Affairs, Veterans Health Administration. As the Under Secretary for Health, he was the highest ranking physician in the federal government and the chief executive officer of the health care system in the United States. His professional experience before joining the U.S. Department of Veterans Affairs included serving on the boards of Health Systems International, Inc., and The California Wellness Foundation. He is board-certified in five medical specialties and has authored over 300 articles, book chapters, and other reports in the medical literature. Dr. Kizer has held senior academic positions at the University of California, Davis, and continues as an Adjunct Professor of Public Policy at the University of Southern California. He is a fellow of the American College of Emergency Physicians, the American

College of Occupational and Environmental Medicine, the Royal Society of Health, and the Royal Society of Medicine. Dr. Kizer is an honors graduate of Stanford University and the University of California, Los Angeles.

WILLIAM KOHLBRENNER, Ph.D., is Director of Antiviral Research in the Pharmaceutical Products Division at Abbott Laboratories in North Chicago, Ill. He received his Ph.D. from the State University of New York and completed postdoctoral training at the Molecular Biology Institute at the University of California, Los Angeles. Dr. Kohlbrenner has contributed to a number of industrial research programs focused on the discovery of novel antibacterial and antiviral agents. He has coauthored many articles on the fundamental aspects of various microbial therapeutic targets and the molecular basis of drug action. He has a strong interest in the development of resistance to antimicrobial agents and in devising appropriate therapeutic strategies for effectively dealing with drug resistance problems.

JOHN R. LaMONTAGNE, Ph.D., is Deputy Director of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. Previously, Dr. LaMontagne was Director of the Division of Microbiology and Infectious Diseases at NIAID. Within NIAID, he has also served as Director of the AIDS Program and Influenza Program Officer. Dr. LaMontagne received his Ph.D. in microbiology from Tulane University and did a postdoctoral fellowship in the laboratory of Julius Youngner at the University of Pittsburgh. There he devoted his efforts to the characterization of viral products produced by cells persistently infected with Newcastle disease virus. His interests are in vaccine research and development.

MARCELLE LAYTON, M.D., is the Assistant Commissioner for the Bureau of Communicable Diseases at the New York City Department of Health. This Bureau is responsible for the surveillance and control of 51 infectious diseases and conditions reportable under the New York City Health Code. Current areas of concern include antibiotic resistance; foodborne, waterborne, and tickborne diseases; hepatitis C and biological disaster planning for the potential threats of bioterrorism and pandemic influenza. Dr. Layton received her medical degree from Duke University. She completed an internal medicine residency at the University Health Science Center in Syracuse, N.Y., and an infectious disease fellowship at Yale University. In addition, Dr. Layton spent 2 years with the Centers for Disease Control and Prevention as a fellow in the Epidemic Intelligence Service, where she was assigned to the New York City Department of Health. In the past, she has volunteered or worked with the Indian Health Service, the Alaskan Native Health Service, and clinics in northwestern Thailand and central Nepal.

CARLOS LOPEZ, Ph.D., is Research Fellow, Research Acquisitions, Eli Lilly Research Laboratories. He received his Ph.D. from the University of Minnesota in 1970. Dr. Lopez was awarded the NTRDA postdoctoral fellowship. After his fellowship he was appointed Assistant Professor of Pathology at the University of Minnesota, where he did his research on cytomegalovirus infections in renal transplant recipients and the consequences of those infections. He was also appointed assistant member and head of the Laboratory of Herpesvirus Infections at the Sloan Kettering Institute for Cancer Research, where his research focused on herpesvirus infections and the mechanisms involved. Dr. Lopez's laboratory contributed to the immunological analysis of the earliest AIDS patients at the beginning of the AIDS epidemic in New York. He is coauthor of one of the seminal publications on this disease, as well as many scientific papers and coeditor of six books. Dr. Lopez has held consultantcies with numerous agencies and organizations including the National Institutes of Health, the U.S. Department of Veterans Affairs, and the American Cancer Society.

STEPHEN S. MORSE, Ph.D., is a Program Manager in the Defense Sciences Office at the Defense Advanced Research Projects Agency (DARPA). Dr. Morse is also Assistant Professor of Virology at The Rockefeller University, where he has been since 1985. In July 1996, he joined the faculty of Columbia University School of Public Health, Division of Epidemiology. Dr. Morse is a virologist and immunologist with research interests in viral effects on T-lymphocyte development and function, viral zoonoses, and methods for studying viral evolution. He was principal organizer and Chair of the 1989 Conference on Emerging Viruses at the National Institutes of Health, and is a member of the Institute of Medicine Committee on Emerging Infections (1990–1992), a current member of the Institute of Medicine Committee on Xenograft Transplantation, and Chair of the Microbiology Section of the New York Academy of Sciences. He is Chair of ProMed (Program for Monitoring Emerging Infections), formed in January 1993, to encourage development of initiatives for anticipating and responding to worldwide emerging infections.

SOLOMON MOWSHOWITZ, Ph.D., is President of Diligen, a New York City biotech consultancy. Diligen performs due diligence in biotechnology, as well as technical consulting, grant writing, technology transfer, and opportunity assessment. Dr. Mowshowitz received his Ph.D. in biochemistry from the Albert Einstein College of Medicine in 1970, and is licensed to practice before the United States Patent and Trademark Office. He taught microbiology and infectious diseases at the Mount Sinai School of Medicine in New York from 1970 to 1984. Beginning in 1985, he held senior positions at a series of commercial biotechnology firms, most recently serving as Vice President, Research and Development at AMBI, Inc. until 1998. Dr. Mowshowitz's primary expertise is in

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STUART L. NIGHTINGALE, M.D., is Associate Commissioner for Health Affairs, U.S. Food and Drug Administration, U.S. Department of Health and Human Services. Dr. Nightingale earned his M.D. degree from New York University School of Medicine and then served as intern (mixed medicine) at Montefiore Hospital and Medical Center in New York, as a resident in internal medicine (including 1 year as a fellow in adolescent medicine) at Montefiore Hospital and Medical Center, and as a resident in anatomical pathology at New York University School of Medicine. He is board-certified in internal medicine, a fellow of the American College of Physicians, and a member of the American Medical Association and the American Public Health Association. Dr. Nightingale heads the Office of Health Affairs of the U.S. Food and Drug Administration (FDA), after prior appointments at several universities, the National Institute of Drug Abuse, and the Executive Office of the President of the United States. Dr. Nightingale has published numerous articles on the impact of federal and state legislation and regulations on medical practice, health fraud, protection of human subjects of research, policy formulation and drug regulation, safety and efficacy determinations and the health effects of FDA-regulated products, and drug abuse prevention. He has received the Award for Distinguished Service, Special Action Office for Drug Abuse Prevention, Executive Office of the President, the Public Health Service Superior Service Award, and FDA's Award of Merit on three occasions. He received the Achievement Award from the American Association of Physicians for Human Rights and received the Presidential Meritorious Executive Rank Award.

MICHAEL T. OSTERHOLM, Ph.D., M.P.H., is the Chairman and Chief Executive Officer of Infection Control Advisory Network, Minnesota. Previously, Dr. Osterholm was the State Epidemiologist and Chief of the Acute Disease Epidemiology Section for the Minnesota Department of Health. He is also an Adjunct Professor of the Division of Epidemiology, School of Public Health, at the University of Minnesota. He has received numerous research awards from the National Institute of Allergy and Infectious Diseases and the Centers for Disease Control and Prevention (CDC). He serves as Principal Investigator for the CDC-sponsored Emerging Infections Program in Minnesota. He has published more than 140 articles on various emerging infectious disease problems. He is past President of the Council of State and Territorial Epidemiologists and chairs its Committee on Public Health, and is a member of the Board of Scientific Counselors, National Centers for Infectious Diseases, CDC, and a member of the National Advisory Committee on Microbial Criteria for Foods, U.S. Department of Agriculture. He recently served as a member of the Committee on the Department of Defense Persian Gulf War Syndrome Comprehensive Clinical Evaluation Program of the Institute of Medicine.

MARC RUBIN, M.D., joined Glaxo Inc in 1990 as Director of Anti-Infectives. From 1991–1995 he was Director of Infectious Diseases and Clinical Research, and from 1995–1997 was International Director and Vice President of Infectious Diseases and Rheumatology. In 1997, he became Vice President of U.S. Clinical Research and in 1998 became Vice President, Infectious Diseases and Hepatitis, Therapeutic Development and Product Strategy, Glaxo Medical, Regulatory and Product Strategy. He received his B.A. in biology from Cornell University and his medical degree from Cornell University Medical School. Dr. Rubin completed his internship and residency at The Johns Hopkins Hospital, Department of Internal Medicine and his fellowship and postdoctoral work at the National Cancer Institute. He is board-certified in internal medicine, oncology, and infectious diseases.

DAVID M. SHLAES, M.D., Ph.D., is Vice President for Infectious Diseases Research at Wyeth-Ayerst Research. Before joining Wyeth-Ayerst, Dr. Shlaes was Professor of Medicine at the Case Western Reserve University School of Medicine and Chief of the Infectious Diseases Section and the Clinical Microbiology Unit at the Veterans Affairs Medical Center in Cleveland, Ohio. He has served a grant reviewer for the U.S. Department of Veterans Affairs Infectious Diseases Merit Review Board and the National Institutes of Health Special Study Section on Biology of Mycobacteria. He has published widely in peer-reviewed journals, and his interest is in antimicrobial agents and chemotherapy and antibiotic resistance.

JANET SHOEMAKER is Director of the American Society for Microbiology's Public Affairs Office, a position she has held since 1989. She is responsible for managing the legislative and regulatory affairs of this 42,000-member organization, the largest single biological science society in the world. She has served as Principal Investigator for a project funded by the National Science Foundation (NSF) to collect and disseminate data on the job market for recent doctorates in microbiology and has played a key role in American Society for Microbiology (ASM) projects, including the production of the ASM *Employment Outlook in the Microbiological Sciences* and *The Impact of Managed Care and Health System Change on Clinical Microbiology*. Previously, she held positions as Assistant Director of Public Affairs for ASM, as ASM coordinator of the U.S./USSR Exchange Program in Microbiology, a program sponsored and coordinated by the National Science Foundation and the U.S. Department of State, and as a freelance editor and writer. She received her baccalaureate, cum laude, from the University of Massachusetts, and is a graduate of the George Washington University programs in public policy and in editing and publications. She has served as commissioner to the Commission on Professionals in Science and Technology, and as the ASM representative to the *ad hoc* Group for Medical Research Funding, and is a member of Women in Government Rela-

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JOHN D. SIEGFRIED, M.D., is Associate Vice President for Medical, Regulatory and Scientific Affairs at Pharmaceutical Research and Manufacturers of America. Dr. Siegfried is a pediatrician with 25 years in clinical practice and for the past decade has been involved with pharmaceutical research and development in the medical and regulatory affairs section of the R.W. Johnson Pharmaceutical Research Institute. He began his career with the U.S. Public Health Service as Medical Officer on the Rosebud and the Redlake Indian Reservations, and completed his active pediatric practice as Chief of Pediatrics and Chief of the Medical Staff at the Al Hada Hospital and Rehabilitation Center in Taif, Saudi Arabia. As a volunteer physician, Dr. Siegfried regularly staffs the Whitman-Walker AIDS Clinic in the District of Columbia as well as its clinic for sexually transmitted diseases.

P. FREDERICK SPARLING, M.D., is a J. Herbert Bate Professor of Medicine, Microbiology and Immunology at the University of North Carolina (UNC) at Chapel Hill and is Director of the North Carolina Sexually Transmitted Infections Research Center. Previously he served as Chair of the Department of Medicine and Chair of the Department of Microbiology and Immunology at UNC. He was president of the Infectious Disease Society of American in 1996–1997. He was also a member of the Institute of Medicine's Committee on Microbial Threats to Health (1991–1992). Dr. Sparling's laboratory research is in the molecular biology of bacterial outer membrane proteins involved in pathogenesis, with a major emphasis on gonococci and meningococci. His current studies focus on the biochemistry and genetics of iron-scavenging mechanisms used by gonococci and meningococci and the structure and function of the gonococcal prion proteins. He is pursuing the goal of a vaccine for gonorrhea.

C. DOUGLAS WEBB, JR., Ph.D., received his bachelor's degree in Biology from Emory University and his master's and doctoral degrees in Microbiology from the University of Georgia. He served in the public health service at the Centers for Disease Control and Prevention (CDC) as both a research microbiologist and supervisory microbiologist. After the CDC, Dr. Webb went to Pfizer Pharmaceuticals and was involved in the development of ampicillin-sulbactam, carbenicillin, cefoperazone, fluconazole, azithromycin, and trovafloxacin. Dr. Webb is Senior Medical Director in Infectious Diseases Global Marketing at Bristol-Myers Squibb, working on the strategy and development for the anti-infective portfolio including human immunodeficiency virus products.

CATHERINE E. WOTEKI, Ph.D., is Undersecretary for Food Safety for the U.S. Department of Agriculture. Prior to receiving Senate confirmation to her present position on July 31, 1997, she served as Acting Undersecretary for Research, Education, and Economics. From 1994 to 1995, she was Deputy to the Associate Director of Science of the Office of Science and Technology Policy. From 1990 to 1994, she was Director of the Food and Nutrition Board, Institute of Medicine, National Academy of Sciences. A biology and chemistry major at Mary Washington College in Fredericksburg, Virginia, she pursued graduate studies in human nutrition at Virginia Polytechnic Institute and State University, Blacksburg, Virginia, and received a Ph.D. in human nutrition. She is a registered dietitian. For 2 years, she performed clinical research in the Department of Medicine of the University of Texas Medical School at San Antonio. She was appointed assistant professor in the Department of Nutrition and Food Science at Drexel University in Philadelphia in 1975. In July 1977, she joined the congressional Office of Technology Assessment as Nutrition Project Director. From 1980 to 1983, she worked for the U.S. Department of Agriculture in two capacities: as leader of the Food and Diet Appraisal Research Group in the Consumer Nutrition Center, and as Acting Associate Administrator of the Human Nutrition Information Service. Dr. Woteki was Deputy Director of the Division of Health Examination Statistics, National Center for Health Statistics, U.S. Department of Health and Human Services, from 1983 to 1990. Dr. Woteki has published 48 articles and numerous technical reports and books on food and nutrition policy and nutrition monitoring. She is the co-editor of *Eat for Life: The Food and Nutrition Board's Guide to Reducing Your Risk of Chronic Disease*. Dr. Woteki is a member of the Institute of Medicine of The National Academies.

STUDY STAFF

JONATHAN R. DAVIS, Ph.D., is a Senior Program Officer at the Institute of Medicine (IOM). His primary charge is as the Study Director of IOM's Forum on Emerging Infections and the Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Dr. Davis was formerly the Science Officer for the Emerging Infectious Diseases and HIV/AIDS Program in the U.S. Department of State's Bureau of Oceans and International Environmental and Scientific Affairs. Prior to his work at the State Department, Dr. Davis was an Assistant Professor of Medicine and Head of the Malaria Laboratory at the University of Maryland School of Medicine where he was the principle and co-principle investigator on grants investigating the fundamental biology of malaria transmission, and on the development and testing of candidate malaria vaccines in human volunteers. Dr. Davis has a M.S. in Medical Entomology from Clemson University, and a Ph.D. in Immunology and Infectious Diseases from The Johns Hopkins University School of Hygiene and Public Health. Dr. Davis is an *ad hoc* reviewer for several professional scientific journals, and currently holds

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VIVIAN P. NOLAN, M.A., is the Research Associate for the Forum on Emerging Infections and for the Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Before joining the Institute of Medicine (IOM), Ms. Nolan was a Science Assistant in the Division of Environmental Biology at the National Science Foundation (NSF) where she worked on grants administration, research projects, and policy analyses on environmental and conservation biology issues. Ms. Nolan is a recipient of a NSF Directors Award for the policy-oriented, interdisciplinary Water and Watersheds collaborative NSF-U.S. Environmental Protection Agency grants program. Ms. Nolan is pursuing her doctorate degree in environmental science and public policy from George Mason University. Her graduate work has included research and policy analysis on issues including environmental, biodiversity conservation, sustainable development, human health, and emerging and reemerging infectious diseases. In August 1998, she participated in an educational program in Kenya that studied the relationship between ecological degradation and emerging infectious diseases. Ms. Nolan was awarded an M.A. in science, technology and public policy in 1994 from the George Washington University, and in 1987 she simultaneously earned two bachelor's degrees in international studies and Latin American studies.

NICOLE AMADO was the Project Assistant for the Institute of Medicine's (IOM) Forum on Emerging Infections and for the IOM Roundtable on Research and Development of Drugs, Biologics, and Medical Devices. Ms. Amado was formerly a Project Coordinator for the Cystic Fibrosis Foundation. Prior to her work at the Cystic Fibrosis Foundation, she was a Panel Assistant with the Chemical Manufacturers Association. Ms. Amado has considerable experience in project organization, research and analysis, and administrative problem solving. Ms. Amado earned a bachelor's degree in biology from the University of Louisville in 1994.